Clinical trial results:
An open-label Phase I/IIa study to evaluate the safety and efficacy of CCS1477 as monotherapy and in combination in patients with advanced solid/metastatic tumours

Summary

EudraCT number	2018-000285-10
Trial protocol	FR ES
Global end of trial date	06 July 2025

Results information

Result version number	v1 (current)
This version publication date	22 July 2026
First version publication date	22 July 2026

Trial information

Trial identification

Sponsor protocol code	CCS1477-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03568656
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CellCentric Ltd
Sponsor organisation address	Chesterford Research Park, Little Chesterford, Cambridge, United Kingdom, CB10 1XL
Public contact	Study Director , CellCentric Ltd, +44 1799531130, clinical@cellcentric.com
Scientific contact	Study Director , CellCentric Ltd, +44 1799531130, clinical@cellcentric.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 July 2025
Global end of trial reached?	Yes
Global end of trial date	06 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the safety and tolerability of CCS1477 as monotherapy and in combination.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 July 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 190
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Sweden: 5
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	219
EEA total number of subjects	24

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	54
From 65 to 84 years	165

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 310 subjects were screened for this study. Of these, 235 subjects were assigned to a treatment group of which 219 received at least 1 dose of CCS1477 at any dose as either monotherapy or in combination with another product.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: CCS1477 100mg Once Daily

Arm description:

Participants with metastatic castration resistant prostate cancer (mCRPC) received 100 mg (milligrams) of CCS1477 once daily (OD) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 100 mg once daily until disease progression.

Arm title	Part A: CCS1477 100mg, 2/Week

Arm description:

Participants with mCRPC received 100 mg of CCS1477 twice per week (2/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg CCS1477 twice per week (2/week).

Arm title	Part A: CCS1477 100mg, 3 Days on and 4 Days Off

Arm description:

Participants with mCRPC received 100 mg of CCS1477 orally for 3 consecutive days, followed by 4 days (D) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg CCS1477 for 3 consecutive days, followed by 4 days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 100mg, 3/Week

Arm description:

Participants with mCRPC received 100 mg of CCS1477 thrice per week (3/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg CCS1477 thrice per week (3/week) until disease progression.

Arm title	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off

Arm description:

Participants with mCRPC received 50 mg of CCS1477 BD orally for 3 consecutive days, followed by 4Ds off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 50mg CCS1477 twice daily (BD) for 3 consecutive days, followed by 4 days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 50mg Once Daily

Arm description:

Participants with mCRPC received 50 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50mg once daily until disease progression.

Arm title	Part A: CCS1477 25mg BD, Daily

Arm description:

Participants with mCRPC received 25 mg of CCS1477 BD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 25mg twice daily (BD) until disease progression.

Arm title	Part A: CCS1477 25mg Once Daily

Arm description:

Participants with mCRPC received 25 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 25mg once daily until disease progression.

Arm title	Part A: CCS1477 50mg, 4 Days on and 3 Days Off

Arm description:

Participants with mCRPC received 50 mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50mg once daily for 4 consecutive days, followed by 3days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 50mg, 5 Days on and 2 Days Off

Arm description:

Participants with mCRPC received 50 mg of CCS1477 OD orally for 5 consecutive days, followed by 2D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50mg once daily for 5 consecutive days, followed by 2days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off

Arm description:

Participants with mCRPC received 50 mg (10mg-Modified formulation (MF)/20mg-MF) of CCS1477 OD orally for 4 consecutive days, followed by 3) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50 mg (10mg-Modified formulation/20mg-Modified formulation) of CCS1477 once daily for 4 consecutive days, followed by 3 days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS147750 mg-MF, 4D on and 3D Off

Arm description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50 mg-MF once daily for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 30mg-MF,4 Days on and 3D Off

Arm description:

Participants with mCRPC received 30 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 30 mg - MF once daily for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off

Arm description:

Participants with mCRPC received 75 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 75 mg -Modified Formulation once daily for 4 consecutive days, followed by 3 days off, and continued on this schedule until disease progression.

Arm title	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off

Arm description:

Participants with mCRPC received 50 mg -MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50 mg -Modified Formulation twice daily (BD) for 4 consecutive days, followed by 3 days off, and continued on this schedule until disease progression.

Arm title	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off

Arm description:

Participants with mCRPC received 35 mg -MF of CCS1477 BD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 35 mg - Modified Formulation twice daily (BD) for 10 consecutive days, followed by 4 days off, and continued on this schedule until disease progression.

Arm title	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off

Arm description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50 mg -Modified Formulation once daily (OD) for 10 consecutive days, followed by 4 days off, and continued on this schedule until disease progression.

Arm title	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off

Arm description:

Participants with mCRPC received recommended Phase II dose of 35mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 35 mg CCS1477 - MF BD for 4 consecutive days, followed by 3 days off, and continued on this schedule until disease progression.

Arm title	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received CCS1477 50 mg- MF administered once daily for 4 consecutive days followed by 3 days off.

Investigational medicinal product name	Abiraterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients received abiraterone 1000 mg once daily on a continuous schedule along with CCS1477, 50mg MF.

Arm title	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 35mg CCS1477 MF, administered twice daily (BD) for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Abiraterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In addition, participants received abiraterone 1000 mg once daily on a continuous schedule along with CCS1477, 35mg MF.

Arm title	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In addition, participants received enzalutamide 160 mg once daily on a continuous schedule along with CCS1477, 50mg MF.

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

In addition, participants received 50mg CCS1477 MF, administered once daily for 4consecutive days followed by 3D off.

Arm title	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

In addition, participants received 75mg CCS1477 MF, administered once daily for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg orally OD on a continuous schedule along with 50mg CCS1477 MF.

Arm title	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 100mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100mg CCS1477 MF, administered once daily for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg orally once daily on a continuous schedule along with 100 mg CCS1477 MF.

Arm title	Part D1: CCS1477 75mg-MF + Enzalutamide Daily

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg once daily on a continuous schedule along with 75mg CCS1477 MF.

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 75mg CCS1477 MF, administered once daily.

Arm title	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 75mg CCS1477 MF, administered twice daily for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg OD on a continuous schedule along with 75mg CCS1477 MF.

Arm title	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg and 75 mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 35mg and 75mg CCS1477 MF, administered orally twice daily for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg once daily on a continuous schedule along with CCS1477, 35mg and 75mg CCS1477 MF.

Arm title	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 10 consecutive days followed by 4D off. In addition, participants received Enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 50mg CCS1477 MF, administered once daily for 10 consecutive days followed by 4D off.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received enzalutamide 160 mg once daily on a continuous schedule along with CCS1477, 50mg CCS1477 MF.

Arm title	Part E1: CCS1477 50mg Daily, 4D on and 3D Off

Arm description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 50 mg CCS1477 OD for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part E1: CCS1477 50mg-MF, 4D on and 3D Off

Arm description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 50mg CCS1477 MF OD for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part E1: CCS1477 75mg-MF, 4D on and 3D Off

Arm description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 75mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 75mg CCS1477 MF OD for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off

Arm description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 35 mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Arm type	Experimental

Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 35mg CCS1477 MF BD for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression.

Arm title	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 25mg CCS1477 MF, administered BD for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Darolutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received darolutamide 600 mg BD on a continuous schedule along with CCS1477, 25mg CCS1477 MF.

Arm title	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off

Arm description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 35mg CCS1477 MF, administered BD for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Darolutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received darolutamide 600 mg BD on a continuous schedule along with CCS1477, 35mg CCS1477 MF.

Arm title	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D

	Off

Arm description:

Participants with non-small cell lung cancer (NSCLC) received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received Atezolizumab 840 mg (once every 2 weeks), 1200 mg (once every 3 weeks) and 1680 mg (once every 4 weeks) intravenously on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Arm type	Experimental
Investigational medicinal product name	CCS1477
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 25mg CCS1477 MF, administered BD for 4 consecutive days followed by 3D off.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Participants received atezolizumab 840 mg (once every 2 weeks), 1200 mg (once every 3 weeks) and 1680 mg (once every 4 weeks) on a continuous schedule.

Number of subjects in period 1	Part A: CCS1477 100mg Once Daily	Part A: CCS1477 100mg, 2/Week	Part A: CCS1477 100mg, 3 Days on and 4 Days Off
Started	4	4	8
Completed	0	0	0
Not completed	4	4	8
Adverse event, serious fatal	4	3	8
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	1	-
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: CCS1477 100mg, 3/Week	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off	Part A: CCS1477 50mg Once Daily
Started	4	8	8
Completed	0	0	0
Not completed	4	8	8
Adverse event, serious fatal	4	7	8
Consent withdrawn by subject	-	-	-

Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	1	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: CCS1477 25mg BD, Daily	Part A: CCS1477 25mg Once Daily	Part A: CCS1477 50mg, 4 Days on and 3 Days Off
Started	6	6	6
Completed	0	0	0
Not completed	6	6	6
Adverse event, serious fatal	6	6	5
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	-	1
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: CCS1477 50mg, 5 Days on and 2 Days Off	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off	Part A: CCS147750 mg-MF, 4D on and 3D Off
Started	4	5	7
Completed	0	0	0
Not completed	4	5	7
Adverse event, serious fatal	4	4	6
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	1	1
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: CCS1477 30mg-MF,4 Days on and 3D Off	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off
Started	5	5	2
Completed	0	0	0
Not completed	5	5	2
Adverse event, serious fatal	5	5	2

Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off
Started	2	2	23
Completed	0	0	0
Not completed	2	2	23
Adverse event, serious fatal	2	2	19
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	3
Unspecified	-	-	-
Lost to follow-up	-	-	1
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off
Started	8	7	7
Completed	0	0	0
Not completed	8	7	7
Adverse event, serious fatal	7	3	5
Consent withdrawn by subject	-	1	-
Abiraterone/Enzalutamide Responder	-	-	2
Study terminated by sponsor	-	-	-
Unspecified	-	-	-
Lost to follow-up	1	-	-
Progressive disease	-	3	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off	Part D1: CCS1477 75mg-MF + Enzalutamide Daily
Started	9	2	3

Completed	0	0	0
Not completed	9	2	3
Adverse event, serious fatal	5	1	3
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	3	1	-
Study terminated by sponsor	-	-	-
Unspecified	1	-	-
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D Off	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off
Started	6	5	4
Completed	0	0	0
Not completed	6	5	4
Adverse event, serious fatal	4	4	4
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	2	1	-
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part E1: CCS1477 50mg Daily, 4D on and 3D Off	Part E1: CCS1477 50mg-MF, 4D on and 3D Off	Part E1: CCS1477 75mg-MF, 4D on and 3D Off
Started	1	1	6
Completed	0	0	0
Not completed	1	1	6
Adverse event, serious fatal	1	-	6
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-
Progressive disease	-	-	-
Protocol deviation	-	1	-

Number of subjects in period 1	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D

	Off	and 3D Off	on and 3D Off
Started	36	4	4
Completed	0	0	0
Not completed	36	4	4
Adverse event, serious fatal	20	3	-
Consent withdrawn by subject	-	-	-
Abiraterone/Enzalutamide Responder	-	-	-
Study terminated by sponsor	9	-	-
Unspecified	3	1	4
Lost to follow-up	4	-	-
Progressive disease	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off
Started	7
Completed	0
Not completed	7
Adverse event, serious fatal	4
Consent withdrawn by subject	-
Abiraterone/Enzalutamide Responder	-
Study terminated by sponsor	-
Unspecified	3
Lost to follow-up	-
Progressive disease	-
Protocol deviation	-

Reporting groups

Reporting group title	Part A: CCS1477 100mg Once Daily

Reporting group description:

Participants with metastatic castration resistant prostate cancer (mCRPC) received 100 mg (milligrams) of CCS1477 once daily (OD) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Reporting group title	Part A: CCS1477 100mg, 2/Week

Reporting group description:

Participants with mCRPC received 100 mg of CCS1477 twice per week (2/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Reporting group title	Part A: CCS1477 100mg, 3 Days on and 4 Days Off

Reporting group description:

Participants with mCRPC received 100 mg of CCS1477 orally for 3 consecutive days, followed by 4 days (D) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 100mg, 3/Week

Reporting group description:

Participants with mCRPC received 100 mg of CCS1477 thrice per week (3/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Reporting group title	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off

Reporting group description:

Participants with mCRPC received 50 mg of CCS1477 BD orally for 3 consecutive days, followed by 4Ds off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 50mg Once Daily

Reporting group description:

Participants with mCRPC received 50 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Reporting group title	Part A: CCS1477 25mg BD, Daily

Reporting group description:

Participants with mCRPC received 25 mg of CCS1477 BD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 25mg Once Daily

Reporting group description:

Participants with mCRPC received 25 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.

Reporting group title	Part A: CCS1477 50mg, 4 Days on and 3 Days Off

Reporting group description:

Participants with mCRPC received 50 mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 50mg, 5 Days on and 2 Days Off

Reporting group description:

Participants with mCRPC received 50 mg of CCS1477 OD orally for 5 consecutive days, followed by 2D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off

Reporting group description:

Participants with mCRPC received 50 mg (10mg-Modified formulation (MF)/20mg-MF) of CCS1477 OD orally for 4 consecutive days, followed by 3) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS147750 mg-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 30mg-MF,4 Days on and 3D Off

Reporting group description:

Participants with mCRPC received 30 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off

Reporting group description:

Participants with mCRPC received 75 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off

Reporting group description:

Participants with mCRPC received 35 mg -MF of CCS1477 BD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received recommended Phase II dose of 35mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Reporting group title	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160

mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 100mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 75mg-MF + Enzalutamide Daily

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg and 75 mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 10 consecutive days followed by 4D off. In addition, participants received Enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part E1: CCS1477 50mg Daily, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1: CCS1477 50mg-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1: CCS1477 75mg-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 75mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 35 mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Reporting group title	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received Atezolizumab 840 mg (once every 2 weeks), 1200 mg (once every 3 weeks) and 1680 mg (once every 4 weeks) intravenously on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Reporting group values	Part A: CCS1477 100mg Once Daily	Part A: CCS1477 100mg, 2/Week	Part A: CCS1477 100mg, 3 Days on and 4 Days Off
Number of subjects	4	4	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	3
From 65-84 years	3	3	5
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	4	4	8
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	4	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A: CCS1477 100mg, 3/Week	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off	Part A: CCS1477 50mg Once Daily
Number of subjects	4	8	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	2
From 65-84 years	4	8	6
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	4	8	8
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	8	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A: CCS1477 25mg BD, Daily	Part A: CCS1477 25mg Once Daily	Part A: CCS1477 50mg, 4 Days on and 3 Days Off
Number of subjects	6	6	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	1	0
From 65-84 years	4	5	6
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	6

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	6	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A: CCS1477 50mg, 5 Days on and 2 Days Off	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off	Part A: CCS147750 mg-MF, 4D on and 3D Off
Number of subjects	4	5	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	2	1
From 65-84 years	2	3	6
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	4	5	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	4	5	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A: CCS1477 30mg-MF,4 Days on and 3D Off	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off
Number of subjects	5	5	2
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	5	5	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	5	5	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	5	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off
Number of subjects	2	2	23
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	2
From 65-84 years	2	2	21
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	2	2	23
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	2	23
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off
Number of subjects	8	7	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	1
From 65-84 years	7	6	6
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	7	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	7	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off	Part D1: CCS1477 75mg-MF + Enzalutamide Daily
Number of subjects	9	2	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	1
From 65-84 years	9	2	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0

Male	9	2	3

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	9	2	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D Off	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off
Number of subjects	6	5	4
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	1	3
From 65-84 years	4	4	1
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	5	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	6	5	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part E1: CCS1477 50mg Daily, 4D on and 3D Off	Part E1: CCS1477 50mg-MF, 4D on and 3D Off	Part E1: CCS1477 75mg-MF, 4D on and 3D Off
Number of subjects	1	1	6
Age categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	1	4
From 65-84 years	1	0	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	1	4
Male	1	0	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	1	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off
Number of subjects	36	4	4
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	20	1	0
From 65-84 years	16	3	4
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	24	0	0
Male	12	4	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0

White	21	3	4
More than one race	0	0	0
Unknown or Not Reported	10	0	0

Reporting group values	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off	Total	
Number of subjects	7	219	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	1	54	
From 65-84 years	6	165	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	33	
Male	3	186	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	8	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	3	
White	6	197	
More than one race	0	0	
Unknown or Not Reported	1	11	

End points reporting groups

Reporting group title	Part A: CCS1477 100mg Once Daily
Reporting group description:	
Participants with metastatic castration resistant prostate cancer (mCRPC) received 100 mg (milligrams) of CCS1477 once daily (OD) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.	
Reporting group title	Part A: CCS1477 100mg, 2/Week
Reporting group description:	
Participants with mCRPC received 100 mg of CCS1477 twice per week (2/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.	
Reporting group title	Part A: CCS1477 100mg, 3 Days on and 4 Days Off
Reporting group description:	
Participants with mCRPC received 100 mg of CCS1477 orally for 3 consecutive days, followed by 4 days (D) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	
Reporting group title	Part A: CCS1477 100mg, 3/Week
Reporting group description:	
Participants with mCRPC received 100 mg of CCS1477 thrice per week (3/week) orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.	
Reporting group title	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off
Reporting group description:	
Participants with mCRPC received 50 mg of CCS1477 BD orally for 3 consecutive days, followed by 4Ds off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	
Reporting group title	Part A: CCS1477 50mg Once Daily
Reporting group description:	
Participants with mCRPC received 50 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.	
Reporting group title	Part A: CCS1477 25mg BD, Daily
Reporting group description:	
Participants with mCRPC received 25 mg of CCS1477 BD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	
Reporting group title	Part A: CCS1477 25mg Once Daily
Reporting group description:	
Participants with mCRPC received 25 mg of CCS1477 OD orally until disease progression, unacceptable toxicity, withdrawal of consent, or any criterion for withdrawal from study intervention.	
Reporting group title	Part A: CCS1477 50mg, 4 Days on and 3 Days Off
Reporting group description:	
Participants with mCRPC received 50 mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	
Reporting group title	Part A: CCS1477 50mg, 5 Days on and 2 Days Off
Reporting group description:	
Participants with mCRPC received 50 mg of CCS1477 OD orally for 5 consecutive days, followed by 2D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	
Reporting group title	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off
Reporting group description:	
Participants with mCRPC received 50 mg (10mg-Modified formulation (MF)/20mg-MF) of CCS1477 OD orally for 4 consecutive days, followed by 3) off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.	

Reporting group title	Part A: CCS147750 mg-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 30mg-MF,4 Days on and 3D Off

Reporting group description:

Participants with mCRPC received 30 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off

Reporting group description:

Participants with mCRPC received 75 mg -MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off

Reporting group description:

Participants with mCRPC received 35 mg -MF of CCS1477 BD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off

Reporting group description:

Participants with mCRPC received 50 mg -MF of CCS1477 OD orally for 10 consecutive days, followed by 4D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received recommended Phase II dose of 35mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Reporting group title	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received abiraterone 1000 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160

mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 100mg MF, administered orally OD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 75mg-MF + Enzalutamide Daily

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally OD. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 75mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg and 75 mg MF, administered orally BD for 4 consecutive days followed by 3D off. In addition, participants received enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 50mg MF, administered orally OD for 10 consecutive days followed by 4D off. In addition, participants received Enzalutamide 160 mg orally OD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part E1: CCS1477 50mg Daily, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1: CCS1477 50mg-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1: CCS1477 75mg-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 75mg MF of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study treatment.

Reporting group title	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off

Reporting group description:

Participants with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition received 35 mg - MF of CCS1477 BD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Reporting group title	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off

Reporting group description:

Participants with mCRPC received the recommended Phase II dose of CCS1477, 35mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600 mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study therapy.

Reporting group title	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) received the recommended Phase II dose of CCS1477, 25mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received Atezolizumab 840 mg (once every 2 weeks), 1200 mg (once every 3 weeks) and 1680 mg (once every 4 weeks) intravenously on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part A and B1: CCS1477 Monotherapy
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with metastatic castration-resistant prostate cancer (mCRPC) received CCS1477 as monotherapy in part A and B1 of the study. CCS1477 was administered orally at 100mg OD or 100mg, 2/week or 100mg, 3 days on and 4 days off or 100mg, 3/week or 50mg BD, 3D on and 4D off or 50mg OD or 25mg BD, daily or 25mg OD or 50mg, 4D on and 3D off or 50mg, 5D on and 2D off or (10mg-MF/20mg-MF) 50mg, 4D on and 3D off or 50mg-MF, 4 days on and 3D off or30mg - MF, 4D on and 3D off or 75mg -MF, 4D on and 3D off or 35mg BD-MF, 4D on and 3D off or 50mg BD-MF, 4D on and 3D off or 35mg BD-MF, 10D on and 4D off or 50mg OD-MF, 10D on and 4D off or 35mg BD-MF, 4D on and 3D off. Treatment continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part C1: CCS1477 in Combination With Abiraterone
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with metastatic castrationresistant prostate cancer (mCRPC) received the recommended Phase II dose of CCS1477, 50 mg MF OD or 35 mg MF, administered orally BD, for 4 consecutive days followed by 3 days off. In addition, participants received abiraterone 1000 mg orally OD. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part D1: CCS1477 in Combination With Enzalutamide
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with metastatic castration resistant prostate cancer (mCRPC) received the recommended Phase II dose of CCS1477: OD at 50mg, 75 mg, or 100 mg for 4 days on/3 days off; 75 mg OD continuously; 75 mg BD continuously; or BD at 35 mg or 75 mg for 4D on/3D off or 50 mg 10 day on/4 day off. In addition, participants received enzalutamide 160 mg orally once daily. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part E1 and E2: CCS1477 Monotherapy
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with advanced solid tumors with molecular markers which may indicate potential for response to p300/CBP inhibition received 50mg daily, 4D on and 3D off or 50mg MF, 4D on and 3D off, or 75mg-MF, 4D on and 3D off, 35mg BD-MF, 4D on and 3D off or 35mg BD modified formulation, 4D on and 3D off of CCS1477 OD orally for 4 consecutive days, followed by 3D off, and continued on this schedule until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part F1: CCS1477 in Combination With Darolutamide

Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with metastatic castrationresistant prostate cancer (mCRPC) received the recommended Phase II dose of CCS1477, 25 mg or 35 mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received darolutamide 600mg BD on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Subject analysis set title	Part H1: CCS1477 in Combination With Atezolizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with non-small cell lung cancer (NSCLC) received the recommended Phase II dose of CCS1477, 25 mg MF, administered BD for 4 consecutive days followed by 3D off. In addition, participants received Atezolizumab 840 mg (once every 2 weeks), 1200 mg (once every 3 weeks) and 1680 mg (once every 4 weeks) intravenously on a continuous schedule. Treatment was continued until disease progression, unacceptable toxicity, withdrawal of consent, or any other criterion for discontinuation of study intervention.

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAEs Leading to Withdrawal

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAEs Leading to Withdrawal[1]

End point description:

Adverse Event (AE) was defined any untoward medical occurrence in a participant administered with a study intervention, which does not necessarily have a causal relationship with the treatment. Serious AE (SAE) was defined AE that resulted in any of the following outcomes: death; life threatening; persistent/significant disability/incapacity; initial/prolonged inpatient hospitalization; congenital anomaly/birth defect. TEAEs: TEAEs were defined as those events with onset dates/time occurring after study intervention administration or events that worsen after study intervention administration. TEAEs included serious TEAEs and non-serious TEAEs. Number of participants with TEAEs leading to withdrawal of study intervention was also reported. Safety Analysis Set (SAF) included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From signing informed consent until the end of the follow-up period (Up to 363 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A: CCS1477 100mg Once Daily	Part A: CCS1477 100mg, 2/Week	Part A: CCS1477 100mg, 3 Days on and 4 Days Off	Part A: CCS1477 100mg, 3/Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	8	4
Units: participants				
TEAEs	4	3	8	4
SAEs	4	1	5	3
TEAEs leading to withdrawal of CCS1477	2	0	4	1

End point values	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off	Part A: CCS1477 50mg Once Daily	Part A: CCS1477 25mg BD, Daily	Part A: CCS1477 25mg Once Daily

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	6	6
Units: participants				
TEAEs	8	7	6	6
SAEs	4	4	1	1
TEAEs leading to withdrawal of CCS1477	1	3	0	0

End point values	Part A: CCS1477 50mg, 4 Days on and 3 Days Off	Part A: CCS1477 50mg, 5 Days on and 2 Days Off	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off	Part A: CCS147750 mg-MF, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	7
Units: participants				
TEAEs	6	4	5	7
SAEs	1	2	3	3
TEAEs leading to withdrawal of CCS1477	0	0	0	0

End point values	Part A: CCS1477 30mg-MF,4 Days on and 3D Off	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	2
Units: participants				
TEAEs	5	5	2	2
SAEs	0	4	1	1
TEAEs leading to withdrawal of CCS1477	0	0	0	0

End point values	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	23	8	7
Units: participants				
TEAEs	2	23	8	7
SAEs	1	6	4	3
TEAEs leading to withdrawal of CCS1477	1	1	2	3

End point values	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off	Part D1: CCS1477 75mg-MF + Enzalutamide Daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	9	2	3
Units: participants				
TEAEs	6	8	2	3
SAEs	1	1	0	2
TEAEs leading to withdrawal of CCS1477	0	1	0	0

End point values	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off	Part E1: CCS1477 50mg Daily, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	4	1
Units: participants				
TEAEs	6	5	4	1
SAEs	1	1	0	0
TEAEs leading to withdrawal of CCS1477	0	0	0	0

End point values	Part E1: CCS1477 50mg-MF, 4D on and 3D Off	Part E1: CCS1477 75mg-MF, 4D on and 3D Off	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	6	36	4
Units: participants				
TEAEs	1	6	36	4
SAEs	0	0	15	0
TEAEs leading to withdrawal of CCS1477	0	0	2	0

End point values	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: participants				
TEAEs	4	7		

SAEs	1	5		
TEAEs leading to withdrawal of CCS1477	0	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst Shift in Laboratory Data-Hematology According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades

End point title	Number of Participants With Worst Shift in Laboratory Data-Hematology According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades[2]

End point description:

Adverse events were graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0, where Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening, and Grade 5 = death related to the adverse event. Number of participants with worst shift in hematology according to Common Terminology Criteria for Adverse Events (CTCAE) grades were reported. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From first dose of study drug in Cycle 1 up to and including 28 days after last dose of study intervention (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants				
Platelets, Grade 0 to Grade 1	24	5	2	11
Platelets, Grade 0 to Grade 2	4	0	0	2
Platelets, Grade 0 to Grade 3	3	0	0	0
Platelets, Grade 0 to Grade 4	3	0	0	0
Platelets, Grade 1 to Grade 2	2	0	0	0
Platelets, Grade 1 to Grade 3	2	0	0	0
Platelets, Grade 1 to Grade 4	1	0	0	0
Eosinophils, Grade 0 to Grade 1	21	3	12	0
Neutrophils, Grade 0 to Grade 1	4	0	0	1
Neutrophils, Grade 0 to Grade 2	1	0	0	0
Neutrophils, Grade 0 to Grade 3	1	0	0	0
Neutrophils, Grade 1 to Grade 2	1	0	0	0

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants				
Platelets, Grade 0 to Grade 1	0	2		
Platelets, Grade 0 to Grade 2	0	0		
Platelets, Grade 0 to Grade 3	0	0		
Platelets, Grade 0 to Grade 4	0	0		
Platelets, Grade 1 to Grade 2	0	0		
Platelets, Grade 1 to Grade 3	0	0		
Platelets, Grade 1 to Grade 4	0	0		
Eosinophils, Grade 0 to Grade 1	3	2		
Neutrophils, Grade 0 to Grade 1	1	0		
Neutrophils, Grade 0 to Grade 2	0	0		
Neutrophils, Grade 0 to Grade 3	0	0		
Neutrophils, Grade 1 to Grade 2	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst Shift in Laboratory Data-Biochemistry According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades

End point title	Number of Participants With Worst Shift in Laboratory Data-Biochemistry According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades[3]

End point description:

Adverse events were graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0, where Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening, and Grade 5 = death related to the adverse event. Number of participants with worst shift in biochemistry according to Common Terminology Criteria for Adverse Events (CTCAE) grades were reported. SAF included all participants who received at least 1 dose of CCS1477. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From first dose of study drug in Cycle 1 up to and including 28 days after last dose of study intervention (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants				
Albumin, Grade 0 to Grade 1	12	2	5	7
Albumin, Grade 0 to Grade 2	10	0	0	3
Albumin, Grade 1 to Grade 2	0	0	3	1
Alkaline Phosphatase, Grade 0 to Grade 1	25	2	7	3
Alkaline Phosphatase, Grade 0 to Grade 2	4	1	3	1
Alkaline Phosphatase, Grade 0 to Grade 3	1	0	1	0
Alanine Aminotransferase, Grade 0 to Grade 1	12	0	0	7
Alanine Aminotransferase, Grade 0 to Grade 2	0	0	0	1
Aspartate Aminotransferase, Grade 0 to Grade 1	25	4	4	11
Aspartate Aminotransferase, Grade 0 to Grade 2	1	0	0	1
Aspartate Aminotransferase, Grade 0 to Grade 3	0	0	0	1
Creatinine, Grade 0 to Grade 1	13	2	4	5
Creatinine, Grade 0 to Grade 2	18	0	1	3
Creatinine, Grade 0 to Grade 3	3	0	0	0
Creatinine, Grade 0 to Grade 4	0	0	0	1
Creatinine, Grade 1 to Grade 2	3	0	0	0
Creatinine, Grade 2 to Grade 3	1	0	0	0
Lactate Dehydrogenase, Grade 0 to Grade 1	35	6	9	9
Total Bilirubin, Grade 0 to Grade 1	7	1	4	3
Total Bilirubin, Grade 0 to Grade 2	2	0	0	2
Total Bilirubin, Grade 0 to Grade 3	2	0	1	0
Total Bilirubin, Grade 0 to Grade 4	0	0	0	2

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants				
Albumin, Grade 0 to Grade 1	1	2		
Albumin, Grade 0 to Grade 2	0	1		
Albumin, Grade 1 to Grade 2	1	1		
Alkaline Phosphatase, Grade 0 to Grade 1	2	1		
Alkaline Phosphatase, Grade 0 to Grade 2	0	0		

Alkaline Phosphatase, Grade 0 to Grade 3	0	1		
Alanine Aminotransferase, Grade 0 to Grade 1	0	2		
Alanine Aminotransferase, Grade 0 to Grade 2	0	0		
Aspartate Aminotransferase, Grade 0 to Grade 1	2	2		
Aspartate Aminotransferase, Grade 0 to Grade 2	0	1		
Aspartate Aminotransferase, Grade 0 to Grade 3	0	0		
Creatinine, Grade 0 to Grade 1	1	2		
Creatinine, Grade 0 to Grade 2	1	1		
Creatinine, Grade 0 to Grade 3	0	0		
Creatinine, Grade 0 to Grade 4	0	0		
Creatinine, Grade 1 to Grade 2	0	0		
Creatinine, Grade 2 to Grade 3	0	0		
Lactate Dehydrogenase, Grade 0 to Grade 1	4	2		
Total Bilirubin, Grade 0 to Grade 1	0	1		
Total Bilirubin, Grade 0 to Grade 2	0	0		
Total Bilirubin, Grade 0 to Grade 3	0	0		
Total Bilirubin, Grade 0 to Grade 4	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Clinically Significant Change From Baseline in Laboratory Parameters - Urinalysis

End point title	Number of Participants With Clinically Significant Change From Baseline in Laboratory Parameters - Urinalysis[4]

End point description:

The urinalysis measurements included glucose, protein and blood. Number of participants with clinically significant changes from baseline in urinalysis values were reported. Clinically Significance was decided by investigator. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From first dose of study drug in Cycle 1 up to and including 28 days after last dose of study intervention (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants	0	0	0	0

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Clinically Significant Change From Baseline in Vital Signs

End point title	Number of Participants With Clinically Significant Change From Baseline in Vital Signs[5]

End point description:

The vital signs measurements included blood pressure, heart rate, respiration rate and temperature. Number of participants with clinically significant changes from baseline in vital signs values were reported. Clinically Significance was decided by investigator. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From first dose of study drug in Cycle 1 up to and including 28 days after last dose of study intervention (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles).

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants	0	0	0	0

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst Shift in QTcF According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades

End point title	Number of Participants With Worst Shift in QTcF According to Common Terminology Criteria for Adverse Events (CTCAE)-Version 5 Grades[6]

End point description:

Twelve-lead Electrocardiograms (ECGs) were obtained after the participant was in semi-supine for 5 minutes. Three ECGs were taken at each timepoint at about 1-minute intervals. QTcF was calculated using the Fridericia formula: QTcF = QT ÷ RR^(1/3), where QT is the measured QT interval in milliseconds and RR is the interval between two consecutive R waves on the ECG expressed in seconds. It was categorized as less than equal to (<=) 450 milliseconds (msec), more than (>) 450 to <=480 msec, > 480 to <= 500 msec and > 500 msec. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Primary

End point timeframe:

From first dose of study drug in Cycle 1 up to and including 28 days after last dose of study intervention (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)
Outcome Measure

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants				
<= 450 msec to > 450 - <= 480 msec	20	2	9	4
<= 450 msec to > 480 - <= 500 msec	1	1	2	1
<= 450 msec to > 500 msec	1	0	0	4
> 450 - <= 480 msec to > 480 - <= 500 msec	1	0	2	0

> 450 - <= 480 msec to > 500 msec	2	0	2	0

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants				
<= 450 msec to > 450 - <= 480 msec	2	2		
<= 450 msec to > 480 - <= 500 msec	0	0		
<= 450 msec to > 500 msec	0	0		
> 450 - <= 480 msec to > 480 - <= 500 msec	0	1		
> 450 - <= 480 msec to > 500 msec	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Best Percentage Change From Baseline in Prostate Specific Antigen (PSA) Response in Participants With Metastatic Castration Resistant Prostate Cancer (mCRPC)

End point title	Best Percentage Change From Baseline in Prostate Specific Antigen (PSA) Response in Participants With Metastatic Castration Resistant Prostate Cancer (mCRPC)

End point description:

Best percentage change from baseline was defined as the largest percentage reduction in PSA levels or the smallest percentage increase in PSA levels in the absence of a reduction. The PSA analysis set was applicable for mCRPC participants only and includes all participants who received at least one dose of CCS1477 from Cycle 1 Day 1 onwards and had a PSA measurement at baseline.

End point type	Secondary

End point timeframe:

At Baseline, Cycle 1 Day 1, Day 8, Day 15, Day 22 and Day 1 of every cycle from cycle 2 onwards until treatment discontinuation (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part F1: CCS1477 in Combination With Darolutamide
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	108	15	36	8
Units: percentage change from baseline				
arithmetic mean (standard deviation)	5.39 (± 35.650)	-8.88 (± 39.560)	-2.85 (± 27.712)	-0.89 (± 30.687)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With CTC Response

End point title	Number of Participants With CTC Response

End point description:

CTC response was defined as a change from unfavourable (five or more cells per 7.5 mL of blood) at baseline to favourable (four or fewer cells per 7.5 mL) post treatment. Number of participants with overall response were reported. A participant was determined as having an overall CTC response if they had at least one post baseline assessment of 'CTC response'. The CTC analysis set included all participants who received at least one dose of CCS1477 from Cycle 1 Day 1 onwards and had measurable CTCs at baseline defined as more than equal to 5 cells per 7.5 mL of blood.

End point type	Secondary

End point timeframe:

From Baseline, Cycle 1 Day 1 (Predose), Cycle 2 Day 1, Cycle 3 Day 1, Cycle 5 Day 1 up to disease progression or treatment discontinuation (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	60	11	12	4
Units: participants	6	1	5	0

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point title	Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point description:

Objective response is defined as any participant with measurable disease who has a best overall response of Partial Response (PR) or Complete Response (CR). CR is defined as the disappearance of all Target Lesions (TLs) since baseline. PR is defined as At least a 30% decrease in the sum of diameters of TLs, taking as reference the baseline sum of diameters. SAF included all participants who received at least 1 dose of CCS1477.

End point type	Secondary

End point timeframe:

From day of study intervention in Cycle 1 until progression or censoring date in the absence of progression (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: participants	1	1	0	0

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Radiological Progression Free Survival (rPFS) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point title	Radiological Progression Free Survival (rPFS) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point description:

Radiological progression free survival (rPFS) was defined as the time from the start of treatment with CCS1477 in Cycle 1 until the earliest objective disease progression defined by RECIST 1.1, Prostate Cancer Clinical Trial Working Group 3 (PCWG-3) bone progression or death by any cause in the absence of progression, regardless of whether the participants withdraws from study medication or receives another anti-cancer therapy prior to progression. Kaplan - Meier estimate was used to calculate the rPFS. SAF included all participants who received at least 1 dose of CCS1477. 99999 signifies the number of events were not sufficient to calculate the upper limit of the confidence interval.

End point type	Secondary

End point timeframe:

From day of study intervention in Cycle 1 until progression or censoring date in the absence of progression (Up to 363 weeks) (Cycle length was 4 weeks for Cycles 1–6 and 6 weeks for Cycle 7 and subsequent cycles)

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: months				
median (confidence interval 90%)	2.8 (1.9 to 3.5)	1.9 (1.6 to 3.5)	3.6 (1.9 to 5.5)	1.9 (1.7 to 2.3)

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: months				
median (confidence interval 90%)	2.8 (1.9 to 8.4)	2.9 (1.7 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall survival is defined as the time from the start of treatment with CCS1477 in Cycle 1 until death due to any cause. SAF included all participants who received at least 1 dose of CCS1477. 99999 signifies the number of events were not sufficient to calculate the upper limit of the confidence interval.

End point type	Secondary

End point timeframe:

From start of treatment until death (Up to 363 weeks)

End point values	Part A and B1: CCS1477 Monotherapy	Part C1: CCS1477 in Combination With Abiraterone	Part D1: CCS1477 in Combination With Enzalutamide	Part E1 and E2: CCS1477 Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	109	15	36	44
Units: months				
median (confidence interval 90%)	10.5 (9.30 to 12.00)	14.2 (7.80 to 19.50)	15.4 (10.90 to 17.10)	10.2 (5.80 to 12.60)

End point values	Part F1: CCS1477 in Combination With Darolutamide	Part H1: CCS1477 in Combination With Atezolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	7		
Units: months				
median (confidence interval 90%)	13.8 (13.70 to 99999)	7.2 (1.80 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax)

End point title	Maximum Observed Plasma Concentration (Cmax)

End point description:

Cmax was obtained directly from concentration versus time curve. The Pharmacokinetic (PK) analysis set included all participants who received at least 1 dose of CCS1477 from C1D1 onwards and have at least 1 measured CCS1477 PK concentration post dose from C1D1 onwards with no important protocol deviations that would impact PK. Here, "Number of participants analyzed" signifies those participants who were evaluable for this outcome measure. 99999 signifies geometric coefficient of variation could not be calculated since the number of participants evaluable was 1. Here, "n" signifies participants evaluable at specified timepoints. For C1D1:
n=4,4,8,4,8,8,6,6,5,4,5,7,5,5,2,2,2,23,8,6,7,9,2,3,6,5,4,7,9,2,3,4,4,7 and for C2D3:
n=0,0,0,1,0,5,0,0,0,6,3,0,3,4,3,1,1,0,14,0,0,0,2,0,0,4,3,0,0,0,0,0,0,0,0. 88888 signifies data was not evaluable as no participant was analyzed for this timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (C1D1) and Cycle 2 Day 3 (C2D3) (Cycle length was 4 weeks)

End point values	Part A: CCS1477 100mg Once Daily	Part A: CCS1477 100mg, 2/Week	Part A: CCS1477 100mg, 3 Days on and 4 Days Off	Part A: CCS1477 100mg, 3/Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	8	4
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	708.4 (± 64.0)	1434.1 (± 104.8)	823.1 (± 29.3)	628.5 (± 83.9)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	813 (± 99999)	88888 (± 88888)

End point values	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off	Part A: CCS1477 50mg Once Daily	Part A: CCS1477 25mg BD, Daily	Part A: CCS1477 25mg Once Daily

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	6	6
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	485.7 (± 66.6)	375.5 (± 36.9)	132.1 (± 31.3)	237.6 (± 65.2)
Cycle 2 - Day 3	676.9 (± 58.5)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Part A: CCS1477 50mg, 4 Days on and 3 Days Off	Part A: CCS1477 50mg, 5 Days on and 2 Days Off	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off	Part A: CCS147750 mg-MF, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	7
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	303.7 (± 41.5)	351.4 (± 44.7)	132.6 (± 68.6)	968.6 (± 61.7)
Cycle 2 - Day 3	531.5 (± 51.5)	545.9 (± 51.1)	88888 (± 88888)	847.1 (± 55.6)

End point values	Part A: CCS1477 30mg-MF,4 Days on and 3D Off	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	2
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	515.4 (± 22.7)	1462.9 (± 56.2)	682.9 (± 154.2)	820.0 (± 56.5)
Cycle 2 - Day 3	670.5 (± 21.0)	1515.0 (± 46.6)	1720.0 (± 99999)	1160.0 (± 99999)

End point values	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	23	8	7
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				

Cycle 1 - Day 1	893.7 (± 104.4)	557.5 (± 69.5)	248.0 (± 104.1)	522.4 (± 72.5)
Cycle 2 - Day 3	88888 (± 88888)	633.6 (± 71.6)	88888 (± 88888)	88888 (± 88888)

End point values	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off	Part D1: CCS1477 75mg-MF + Enzalutamide Daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	9	2	3
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	13484.5 (± 68.6)	14717.1 (± 74.1)	15440.9 (± 23.6)	11271.5 (± 97.0)
Cycle 2 - Day 3	88888 (± 88888)	16240.7 (± 4.8)	88888 (± 88888)	88888 (± 88888)

End point values	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off	Part E1: CCS1477 50mg Daily, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	4	1
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	15420.6 (± 20.6)	3449.1 (± 13.2)	17843.4 (± 6.9)	259.1 (± 35.4)
Cycle 2 - Day 3	19770.9 (± 32.3)	16272.2 (± 7.2)	88888 (± 88888)	88888 (± 88888)

End point values	Part E1: CCS1477 50mg-MF, 4D on and 3D Off	Part E1: CCS1477 75mg-MF, 4D on and 3D Off	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	6	36	4
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	344.3 (± 55.4)	301.0 (± 102.9)	427.1 (± 67.5)	3838.6 (± 16.8)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: nanogram/milliliter (ng/ml				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	6140.8 (± 29.6)	702.8 (± 55.6)		
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve From Time Zero to Infinity (AUC0-24)

End point title	Area Under the Plasma Concentration-Time Curve From Time Zero to Infinity (AUC0-24)

End point description:

AUC0-24 is defined as the area under the concentration-time curve (AUC) from time zero (= dosing time) to 24 hours. AUC0-24 was calculated using the mixed log-linear trapezoidal rule. The PK analysis set included all participants who received at least 1 dose of CCS1477 from C1D1 onwards and have at least 1 measured CCS1477 PK concentration post dose from C1D1 onwards with no important protocol deviations that would impact PK. Here, "Number of participants analyzed" signifies those participants who were evaluable for this outcome measure. 99999 signifies geometric coefficient of variation could not be calculated since the number of participants evaluable was 1. Here, "n" signifies participants evaluable at specified timepoints. For C1D1:
n=4,4,8,4,8,8,6,6,5,4,5,7,5,5,2,2,2,23,8,6,7,9,2,3,6,5,4,1,1,6,28,4,4,7 and for C2D3:
n=0,0,1,0,0,0,0,0,6,3,0,3,4,3,0,0,0,0,0,0,0,2,0,0,4,3,0,0,0,0,0,0,0,0,0. 88888 signifies data was not evaluable as no participant was analyzed for this time point.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 and Cycle 2 Day 3 (Cycle length was 4 weeks)

End point values	Part A: CCS1477 100mg Once Daily	Part A: CCS1477 100mg, 2/Week	Part A: CCS1477 100mg, 3 Days on and 4 Days Off	Part A: CCS1477 100mg, 3/Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	8	4
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient				

of variation)				
Cycle 1 - Day 1	5750.4 (± 197.5)	10447.9 (± 137.3)	6755.0 (± 47.1)	5944.7 (± 95.7)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	9543.7 (± 99999)	88888 (± 88888)

End point values	Part A: CCS1477 50mg BD, 3 Days on and 4 Days Off	Part A: CCS1477 50mg Once Daily	Part A: CCS1477 25mg BD, Daily	Part A: CCS1477 25mg Once Daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	6	6
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	3790.5 (± 141.8)	2542.0 (± 59.4)	829.2 (± 81.8)	88888 (± 88888)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	1572.1 (± 88.4)

End point values	Part A: CCS1477 50mg, 4 Days on and 3 Days Off	Part A: CCS1477 50mg, 5 Days on and 2 Days Off	Part A: CCS1477(10mg-MF/20mg-MF) 50mg, 4 D On and 3 D Off	Part A: CCS147750 mg-MF, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	7
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	1776.1 (± 42.1)	3697.1 (± 58.3)	646.4 (± 46.4)	4195.7 (± 97.2)
Cycle 2 - Day 3	3103.8 (± 99.1)	4385.7 (± 36.1)	88888 (± 88888)	3582.3 (± 88.2)

End point values	Part A: CCS1477 30mg-MF,4 Days on and 3D Off	Part A: CCS1477 75mg-MF, 4Days on and 3Days Off	PartA: CCS1477 50mg BD-MF, 4D on and 3D Off	PartA: CCS1477 35mg BD-MF, 10 D on and 4 D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	2
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	2096.7 (± 32.0)	6594.1 (± 89.5)	2873.6 (± 360.0)	3247.1 (± 0.4)

Cycle 2 - Day 3	2813.0 (± 19.2)	8822.0 (± 119.1)	88888 (± 88888)	88888 (± 88888)

End point values	Part A: CCS1477 50mg OD-MF, 10D on and 4D Off	Part A and B1:CCS1477 35mg BD-MF, 4D on and 3D Off	Part C1: CCS1477 50mg - MF + Abiraterone, 4D on and 3D Off	Part C1: CCS1477 35mg-MF BD + Abiraterone, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	23	8	7
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	3732.8 (± 199.4)	3299.2 (± 76.9)	1218.1 (± 93.4)	2492.1 (± 51.7)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Part D1: CCS1477 50mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS14777 75mg-MF + Enzalutamide, 4D on and 3D Off	Part D1: CCS1477 100mg-MF + Enzalutamide, 4 D on and 3D Off	Part D1: CCS1477 75mg-MF + Enzalutamide Daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	9	2	3
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	249370.4 (± 98.4)	269964.2 (± 99.4)	292439.6 (± 14.3)	194471.6 (± 175.9)
Cycle 2 - Day 3	88888 (± 88888)	310130.1 (± 24.6)	88888 (± 88888)	88888 (± 88888)

End point values	Part D1: CCS1477 75mg BD - MF + Enzalutamide, 4D on 3 D Off	Part D1:CCS1477 35mg and 75mg BD-MF+Enzalutamide, 4D on/3D	Part D1:CCS1477 50mg Daily-MF+Enzalutamide, 10 D on and 4D Off	Part E1: CCS1477 50mg Daily, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	4	1
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	308618.7 (± 20.3)	38260.0 (± 25.9)	336943.2 (± 18.1)	2891.8 (± 99999)

Cycle 2 - Day 3	339289.0 (± 37.0)	296836.3 (± 1.0)	88888 (± 88888)	88888 (± 88888)

End point values	Part E1: CCS1477 50mg-MF, 4D on and 3D Off	Part E1: CCS1477 75mg-MF, 4D on and 3D Off	Part E1 and E2: CCS1477 35mg BD-MF, 4D on and 3D Off	Part F1: CCS1477 25mg BD-MF + Darolutamide, 4D on and 3D Off
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	6	36	4
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	3400.8 (± 99999)	8460.4 (± 75.6)	3561.3 (± 114.7)	1334.9 (± 28.9)
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Part F1: CCS1477 35mg BD-MF + Darolutamide, 4 D on and 3D Off	Part H1: CCS1477 25mg BD-MF + Atezolizumab, 4D on and 3D Off		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 - Day 1	1852.9 (± 111.7)	3686.0 (± 48.1)		
Cycle 2 - Day 3	88888 (± 88888)	88888 (± 88888)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to end of study (Up to 363 weeks)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	Part A: 100mg, 2/wk
Reporting group description: -	
Reporting group title	Part A: (10mg-M/20mg-M) 50mg, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 100mg, 3/wk
Reporting group description: -	
Reporting group title	Part A: 100mg, 3d on/4d off
Reporting group description: -	
Reporting group title	Part A: 100mg, daily
Reporting group description: -	
Reporting group title	Part A: 25mg BD, daily
Reporting group description: -	
Reporting group title	Part A: 25mg, daily
Reporting group description: -	
Reporting group title	Part A: 30mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 50mg BD, 3d on/4d off
Reporting group description: -	
Reporting group title	Part A: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 35mg BD-M, 10d on/4d off
Reporting group description: -	
Reporting group title	Part A: 50mg, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 50mg OD-M, 10d on/4d off
Reporting group description: -	
Reporting group title	Part A: 50mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 50mg, 5d on/2d off
Reporting group description: -	
Reporting group title	Part A: 50mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part A: 50mg, daily
Reporting group description: -	
Reporting group title	Part A: 75mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 100mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part C1: 50mg-M, 4d on/3d off

Reporting group description: -	
Reporting group title	Part C1: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part B1: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 35mg BD 75mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 50mg OD-M, 10d on/4d off
Reporting group description: -	
Reporting group title	Part D1: 50mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 75mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 75mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part D1: 75mg-M, daily
Reporting group description: -	
Reporting group title	Part E1: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part E1: 50mg, 4d on/3d off
Reporting group description: -	
Reporting group title	Part E1: 50mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part F1: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part F1: 25mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part E2: 35mg BD-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part E1: 75mg-M, 4d on/3d off
Reporting group description: -	
Reporting group title	Part H1: 25mg BD-M, 4d on/3d off
Reporting group description: -	

Serious adverse events	Part A: 100mg, 2/wk	Part A: (10mg-M/20mg-M) 50mg, 4d on/3d off	Part A: 100mg, 3/wk
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	3 / 5 (60.00%)	3 / 4 (75.00%)
number of deaths (all causes)	3	4	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain	Additional description: Pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea	Additional description: Nausea		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: 100mg, 3d on/4d off	Part A: 100mg, daily	Part A: 25mg BD, daily
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	4 / 4 (100.00%)	1 / 6 (16.67%)
number of deaths (all causes)	8	4	6
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis	Additional description: Stomatitis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	2 / 8 (25.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 8 (12.50%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: 25mg, daily	Part A: 30mg-M, 4d on/3d off	Part A: 50mg BD, 3d on/4d off
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	4 / 8 (50.00%)
number of deaths (all causes)	6	5	7
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pelvic fracture	Additional description: Pelvic fracture		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: 35mg BD-M, 4d on/3d off	Part A: 35mg BD-M, 10d on/4d off	Part A: 50mg, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	1 / 2 (50.00%)	1 / 6 (16.67%)
number of deaths (all causes)	6	2	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: 50mg OD-M, 10d on/4d off	Part A: 50mg BD-M, 4d on/3d off	Part A: 50mg, 5d on/2d off
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	2 / 4 (50.00%)
number of deaths (all causes)	2	2	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: 50mg-M, 4d on/3d off	Part A: 50mg, daily	Part A: 75mg-M, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	4 / 8 (50.00%)	4 / 5 (80.00%)
number of deaths (all causes)	6	8	5
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part D1: 100mg-M, 4d on/3d off	Part C1: 50mg-M, 4d on/3d off	Part C1: 35mg BD-M, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	5 / 8 (62.50%)	3 / 7 (42.86%)
number of deaths (all causes)	1	7	6
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B1: 35mg BD-M, 4d on/3d off	Part D1: 35mg BD 75mg BD-M, 4d on/3d off	Part D1: 50mg OD-M, 10d on/4d off
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 15 (26.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
number of deaths (all causes)	13	4	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part D1: 50mg-M, 4d on/3d off	Part D1: 75mg BD-M, 4d on/3d off	Part D1: 75mg-M, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 9 (11.11%)
number of deaths (all causes)	5	4	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part D1: 75mg-M, daily	Part E1: 35mg BD-M, 4d on/3d off	Part E1: 50mg, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	7 / 16 (43.75%)	0 / 1 (0.00%)
number of deaths (all causes)	3	9	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 3 (33.33%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	2 / 3 (66.67%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part E1: 50mg-M, 4d on/3d off	Part F1: 35mg BD-M, 4d on/3d off	Part F1: 25mg BD-M, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
number of deaths (all causes)	1	0	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part E2: 35mg BD-M, 4d on/3d off	Part E1: 75mg-M, 4d on/3d off	Part H1: 25mg BD-M, 4d on/3d off
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 20 (50.00%)	1 / 6 (16.67%)	5 / 7 (71.43%)
number of deaths (all causes)	11	6	4
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone-refractory prostate cancer	Additional description: Hormone-refractory prostate cancer		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage	Additional description: Tumour haemorrhage		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain	Additional description: Pain		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose	Additional description: Overdose		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture	Additional description: Pelvic fracture		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-associated dyspnoea	Additional description: Transfusion-associated dyspnoea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant spinal cord compression	Additional description: Malignant spinal cord compression		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestinal obstruction	Additional description: Large intestinal obstruction		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting	Additional description: Vomiting

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic haemorrhage	Additional description: Hepatic haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: Urinary tract obstruction		

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin abscess	Additional description: Groin abscess		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection	Additional description: Infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis	Additional description: Pulmonary sepsis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia	Additional description: Staphylococcal bacteraemia		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part A: 100mg, 2/wk	Part A: (10mg-M/20mg-M) 50mg, 4d on/3d off	Part A: 100mg, 3/wk
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	5 / 5 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 4 (25.00%)	4 / 5 (80.00%)	3 / 4 (75.00%)
occurrences (all)	1	4	3
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema	Additional description: Scrotal oedema		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Depression	Additional description: Depression		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	3 / 4 (75.00%)
occurrences (all)	0	0	3
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Contusion	Additional description: Contusion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fall	Additional description: Fall		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	2 / 4 (50.00%)
occurrences (all)	2	1	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: Erythema		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: Rash		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infection	Additional description: Infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 4 (75.00%)
occurrences (all)	0	1	3
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophagia	Additional description: Hypophagia		

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: 100mg, 3d on/4d off	Part A: 100mg, daily	Part A: 25mg BD, daily
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypotension	Additional description: Hypotension		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Chills	Additional description: Chills		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	3 / 8 (37.50%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	3	1	2
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		

subjects affected / exposed	3 / 8 (37.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		

subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tremor	Additional description: Tremor		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	6 / 8 (75.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	6	2	1
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	1	1	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	3 / 8 (37.50%)	4 / 4 (100.00%)	1 / 6 (16.67%)
occurrences (all)	3	4	1
Diarrhoea	Additional description: Diarrhoea		

subjects affected / exposed	3 / 8 (37.50%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	3	1	3
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	4 / 8 (50.00%)	3 / 4 (75.00%)	2 / 6 (33.33%)
occurrences (all)	5	3	2
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		

subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	2 / 8 (25.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 8 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Erythema	Additional description: Erythema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: Rash		
subjects affected / exposed	0 / 8 (0.00%)	3 / 4 (75.00%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		

subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	3
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection	Additional description: Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	1 / 8 (12.50%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	2 / 8 (25.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: 25mg, daily	Part A: 30mg-M, 4d on/3d off	Part A: 50mg BD, 3d on/4d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	5 / 5 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lymphoedema	Additional description: Lymphoedema		

subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: Chills		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	2 / 6 (33.33%)	4 / 5 (80.00%)	3 / 8 (37.50%)
occurrences (all)	2	5	3
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Pain	Additional description: Pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	3
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cough	Additional description: Cough		
subjects affected / exposed	1 / 6 (16.67%)	2 / 5 (40.00%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Depression	Additional description: Depression		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Product issues			
Device occlusion	Additional description: Device occlusion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Blood folate decreased	Additional description: Blood folate decreased		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Weight decreased	Additional description: Weight decreased		

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fall	Additional description: Fall		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Dysgeusia	Additional description: Dysgeusia		

subjects affected / exposed	0 / 6 (0.00%)	2 / 5 (40.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	2
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 8 (25.00%)
occurrences (all)	3	0	3
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Ear discomfort	Additional description: Ear discomfort		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	3 / 6 (50.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	1 / 6 (16.67%)	2 / 5 (40.00%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Dry mouth	Additional description: Dry mouth		

subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	2 / 6 (33.33%)	4 / 5 (80.00%)	6 / 8 (75.00%)
occurrences (all)	2	5	6
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	3 / 8 (37.50%)
occurrences (all)	0	1	3
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Erythema	Additional description: Erythema		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia	Additional description: Palmar-plantar erythrodysaesthesia syndrome		

syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: Rash		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	2
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	2 / 6 (33.33%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	1 / 6 (16.67%)	2 / 5 (40.00%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infection	Additional description: Infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	3 / 6 (50.00%)	2 / 5 (40.00%)	2 / 8 (25.00%)
occurrences (all)	3	2	3
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	2
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: 35mg BD-M, 4d on/3d off	Part A: 35mg BD-M, 10d on/4d off	Part A: 50mg, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	2 / 2 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	2 / 8 (25.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		

subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	4 / 8 (50.00%)	2 / 2 (100.00%)	2 / 6 (33.33%)
occurrences (all)	5	2	2
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 8 (12.50%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	1 / 8 (12.50%)	1 / 2 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase	Additional description: Blood lactate dehydrogenase increased		

increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	2 / 8 (25.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			

Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tachycardia	Additional description: Tachycardia		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		

subjects affected / exposed	4 / 8 (50.00%)	1 / 2 (50.00%)	2 / 6 (33.33%)
occurrences (all)	5	1	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	6 / 8 (75.00%)	0 / 2 (0.00%)	2 / 6 (33.33%)
occurrences (all)	7	0	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	3 / 8 (37.50%)	1 / 2 (50.00%)	2 / 6 (33.33%)
occurrences (all)	3	1	3
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: Erythema		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: Rash		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Bone pain	Additional description: Bone pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	2 / 8 (25.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	2 / 8 (25.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Anal abscess	Additional description: Anal abscess		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gingivitis	Additional description: Gingivitis		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection	Additional description: Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 8 (12.50%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Viral infection	Additional description: Viral infection		

subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	3 / 8 (37.50%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	2 / 8 (25.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	5	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	2 / 8 (25.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 8 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	1 / 8 (12.50%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 8 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: 50mg OD-M, 10d on/4d off	Part A: 50mg BD-M, 4d on/3d off	Part A: 50mg, 5d on/2d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Product issues			
Device occlusion	Additional description: Device occlusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	2 / 4 (50.00%)
occurrences (all)	0	4	2
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 4 (75.00%)
occurrences (all)	0	0	4
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fall	Additional description: Fall		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	3 / 4 (75.00%)
occurrences (all)	1	2	3
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vomiting	Additional description: Vomiting		

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: 50mg-M, 4d on/3d off	Part A: 50mg, daily	Part A: 75mg-M, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	7 / 8 (87.50%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chills	Additional description: Chills		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	5 / 7 (71.43%)	4 / 8 (50.00%)	4 / 5 (80.00%)
occurrences (all)	5	4	5
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	2 / 7 (28.57%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	2 / 7 (28.57%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 7 (0.00%)	3 / 8 (37.50%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Fall	Additional description: Fall		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	1 / 7 (14.29%)	4 / 8 (50.00%)	2 / 5 (40.00%)
occurrences (all)	1	4	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	2 / 7 (28.57%)	0 / 8 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	4 / 7 (57.14%)	2 / 8 (25.00%)	2 / 5 (40.00%)
occurrences (all)	4	2	2
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	3 / 7 (42.86%)	1 / 8 (12.50%)	2 / 5 (40.00%)
occurrences (all)	3	2	2
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	3 / 7 (42.86%)	4 / 8 (50.00%)	2 / 5 (40.00%)
occurrences (all)	3	4	2
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	3 / 7 (42.86%)	1 / 8 (12.50%)	2 / 5 (40.00%)
occurrences (all)	3	1	2
Back pain	Additional description: Back pain		
subjects affected / exposed	3 / 7 (42.86%)	1 / 8 (12.50%)	2 / 5 (40.00%)
occurrences (all)	3	1	2
Bone pain	Additional description: Bone pain		

subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	2 / 7 (28.57%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Infection	Additional description: Infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	2 / 7 (28.57%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	4 / 7 (57.14%)	2 / 8 (25.00%)	3 / 5 (60.00%)
occurrences (all)	5	2	3
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 7 (0.00%)	2 / 8 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	2 / 7 (28.57%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part D1: 100mg-M, 4d on/3d off	Part C1: 50mg-M, 4d on/3d off	Part C1: 35mg BD-M, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	8 / 8 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 2 (50.00%)	4 / 8 (50.00%)	6 / 7 (85.71%)
occurrences (all)	2	4	7
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	3 / 7 (42.86%)
occurrences (all)	0	1	3
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	4
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 2 (50.00%)	1 / 8 (12.50%)	3 / 7 (42.86%)
occurrences (all)	1	1	3
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 2 (0.00%)	3 / 8 (37.50%)	5 / 7 (71.43%)
occurrences (all)	0	5	7
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	6
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	4 / 7 (57.14%)
occurrences (all)	0	2	6
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Retching	Additional description: Retching		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 2 (50.00%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 2 (0.00%)	3 / 8 (37.50%)	4 / 7 (57.14%)
occurrences (all)	0	4	5
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 2 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	5
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	1 / 2 (50.00%)	3 / 8 (37.50%)	4 / 7 (57.14%)
occurrences (all)	1	3	6
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	1 / 2 (50.00%)	0 / 8 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	3
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 2 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B1: 35mg BD-M, 4d on/3d off	Part D1: 35mg BD 75mg BD-M, 4d on/3d off	Part D1: 50mg OD-M, 10d on/4d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)	5 / 5 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	7 / 15 (46.67%)	5 / 5 (100.00%)	3 / 4 (75.00%)
occurrences (all)	12	7	3
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 15 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	1 / 15 (6.67%)	3 / 5 (60.00%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	3 / 15 (20.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fall	Additional description: Fall		
subjects affected / exposed	2 / 15 (13.33%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	1 / 15 (6.67%)	2 / 5 (40.00%)	2 / 4 (50.00%)
occurrences (all)	1	2	2
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	4 / 15 (26.67%)	2 / 5 (40.00%)	2 / 4 (50.00%)
occurrences (all)	4	2	2
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	3 / 15 (20.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Constipation	Additional description: Constipation		
subjects affected / exposed	6 / 15 (40.00%)	3 / 5 (60.00%)	1 / 4 (25.00%)
occurrences (all)	7	7	1
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	6 / 15 (40.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	8	0	0
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	3 / 15 (20.00%)	2 / 5 (40.00%)	4 / 4 (100.00%)
occurrences (all)	6	3	5
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Toothache	Additional description: Toothache		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	3 / 15 (20.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	3	2	1
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	3
Back pain	Additional description: Back pain		
subjects affected / exposed	2 / 15 (13.33%)	5 / 5 (100.00%)	1 / 4 (25.00%)
occurrences (all)	2	6	2
Bone pain	Additional description: Bone pain		

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	1 / 15 (6.67%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	3 / 5 (60.00%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	6 / 15 (40.00%)	5 / 5 (100.00%)	1 / 4 (25.00%)
occurrences (all)	8	6	1
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	2 / 15 (13.33%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	5 / 15 (33.33%)	3 / 5 (60.00%)	0 / 4 (0.00%)
occurrences (all)	8	4	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part D1: 50mg-M, 4d on/3d off	Part D1: 75mg BD-M, 4d on/3d off	Part D1: 75mg-M, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	5 / 6 (83.33%)	8 / 9 (88.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	3 / 7 (42.86%)	3 / 6 (50.00%)	5 / 9 (55.56%)
occurrences (all)	3	3	5
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Depression	Additional description: Depression		
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	3 / 7 (42.86%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	4 / 7 (57.14%)	2 / 6 (33.33%)	0 / 9 (0.00%)
occurrences (all)	4	4	0
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	3 / 9 (33.33%)
occurrences (all)	3	2	3
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	3 / 9 (33.33%)
occurrences (all)	0	1	4
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysuria	Additional description: Dysuria		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	3 / 9 (33.33%)
occurrences (all)	2	1	3
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	2 / 9 (22.22%)
occurrences (all)	4	1	2
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part D1: 75mg-M, daily	Part E1: 35mg BD-M, 4d on/3d off	Part E1: 50mg, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	15 / 16 (93.75%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Chills	Additional description: Chills		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	3 / 3 (100.00%)	4 / 16 (25.00%)	1 / 1 (100.00%)
occurrences (all)	3	4	1
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 3 (0.00%)	4 / 16 (25.00%)	1 / 1 (100.00%)
occurrences (all)	0	4	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 3 (0.00%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	1 / 1 (100.00%)
occurrences (all)	2	0	1
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 3 (0.00%)	10 / 16 (62.50%)	0 / 1 (0.00%)
occurrences (all)	0	10	0
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 3 (0.00%)	4 / 16 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Constipation	Additional description: Constipation		
subjects affected / exposed	2 / 3 (66.67%)	3 / 16 (18.75%)	1 / 1 (100.00%)
occurrences (all)	3	3	1
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	2 / 3 (66.67%)	5 / 16 (31.25%)	1 / 1 (100.00%)
occurrences (all)	3	5	1
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 3 (0.00%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 3 (33.33%)	5 / 16 (31.25%)	0 / 1 (0.00%)
occurrences (all)	1	6	0
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	1 / 3 (33.33%)	6 / 16 (37.50%)	0 / 1 (0.00%)
occurrences (all)	1	7	0
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	2 / 3 (66.67%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	2 / 3 (66.67%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	3	3	0
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 3 (33.33%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	1 / 3 (33.33%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	1 / 3 (33.33%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	1 / 3 (33.33%)	1 / 16 (6.25%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	1 / 3 (33.33%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	1 / 3 (33.33%)	3 / 16 (18.75%)	1 / 1 (100.00%)
occurrences (all)	1	3	1
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 3 (0.00%)	4 / 16 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 3 (33.33%)	5 / 16 (31.25%)	0 / 1 (0.00%)
occurrences (all)	1	5	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part E1: 50mg-M, 4d on/3d off	Part F1: 35mg BD-M, 4d on/3d off	Part F1: 25mg BD-M, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypertension	Additional description: Hypertension		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Chills	Additional description: Chills		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 1 (100.00%)	3 / 4 (75.00%)	3 / 4 (75.00%)
occurrences (all)	2	3	3
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	3
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tremor	Additional description: Tremor		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	1 / 1 (100.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 1 (100.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	1	5	3
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vomiting	Additional description: Vomiting		

subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	2	1	4
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash	Additional description: Rash		
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences (all)	0	2	4
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part E2: 35mg BD-M, 4d on/3d off	Part E1: 75mg-M, 4d on/3d off	Part H1: 25mg BD-M, 4d on/3d off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	6 / 6 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain	Additional description: Tumour pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing	Additional description: Flushing		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: Hot flush		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White coat hypertension	Additional description: White coat hypertension		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	8 / 20 (40.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	9	0	0
Catheter site erythema	Additional description: Catheter site erythema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site irritation	Additional description: Catheter site irritation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site rash	Additional description: Catheter site rash		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction	Additional description: Catheter site related reaction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Chills	Additional description: Chills		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Crepitations	Additional description: Crepitations		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis	Additional description: Device related thrombosis		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety	Additional description: Early satiety		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: Feeling abnormal		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	5 / 20 (25.00%)	3 / 6 (50.00%)	5 / 7 (71.43%)
occurrences (all)	5	3	5
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Feeling jittery	Additional description: Feeling jittery		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hernia pain	Additional description: Hernia pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Pain	Additional description: Pain		
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	6
Swelling face	Additional description: Swelling face		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vaccination site reaction	Additional description: Vaccination site reaction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Genital lesion	Additional description: Genital lesion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema genital	Additional description: Oedema genital		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile discharge	Additional description: Penile discharge		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Penile haemorrhage	Additional description: Penile haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Penile pain	Additional description: Penile pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Penile oedema	Additional description: Penile oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: Cough		

subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Dry throat	Additional description: Dry throat		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	3 / 7 (42.86%)
occurrences (all)	4	0	3
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion	Additional description: Increased bronchial secretion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion	Additional description: Increased upper airway secretion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract inflammation	Additional description: Respiratory tract inflammation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation	Additional description: Agitation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Irritability	Additional description: Irritability		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Mood swings	Additional description: Mood swings		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Personality change	Additional description: Personality change		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion	Additional description: Device occlusion		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	2
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cardiac murmur	Additional description: Cardiac murmur		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave inversion	Additional description: Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged	Additional description: Prothrombin time prolonged		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 20 (0.00%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Injury, poisoning and procedural complications			
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Fall	Additional description: Fall		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail avulsion	Additional description: Nail avulsion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural contusion	Additional description: Post procedural contusion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: Procedural pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury	Additional description: Radiation skin injury		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: Skin laceration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Stoma site discharge	Additional description: Stoma site discharge		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site pain	Additional description: Stoma site pain		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: Tooth fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Sinus bradycardia	Additional description: Sinus bradycardia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		

subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Brain fog	Additional description: Brain fog		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cervical cord compression	Additional description: Cervical cord compression		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	3	1	2
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	3	1	1
Essential tremor	Additional description: Essential tremor		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Headache		
subjects affected / exposed	5 / 20 (25.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	8	0	1
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy	Additional description: Lethargy		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine	Additional description: Ophthalmic migraine		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sensory loss	Additional description: Sensory loss		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: Somnolence		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Spinal cord compression	Additional description: Spinal cord compression		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	6 / 20 (30.00%)	3 / 6 (50.00%)	4 / 7 (57.14%)
occurrences (all)	8	4	8
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophilia	Additional description: Neutrophilia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	2	1	2
Ear and labyrinth disorders			
Deafness bilateral	Additional description: Deafness bilateral		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral	Additional description: Deafness unilateral		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pruritus	Additional description: Ear pruritus		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Motion sickness	Additional description: Motion sickness		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: Conjunctivitis allergic		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eye swelling	Additional description: Eye swelling		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: Abdominal distension		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	3	1	1
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Constipation	Additional description: Constipation		
subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	5 / 7 (71.43%)
occurrences (all)	3	2	6
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	3 / 20 (15.00%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	3	2
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyschezia	Additional description: Dyschezia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Erosive duodenitis	Additional description: Erosive duodenitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis	Additional description: Erosive oesophagitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation	Additional description: Eructation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces soft	Additional description: Faeces soft		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mechanical ileus	Additional description: Mechanical ileus		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	3 / 20 (15.00%)	3 / 6 (50.00%)	5 / 7 (71.43%)
occurrences (all)	3	3	6
Oral pain	Additional description: Oral pain		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal discharge	Additional description: Rectal discharge		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retching	Additional description: Retching		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion	Additional description: Salivary hypersecretion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: Vomiting		

subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	4 / 7 (57.14%)
occurrences (all)	2	1	5
Hepatobiliary disorders			
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Biliary tract disorder	Additional description: Biliary tract disorder		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia	Additional description: Hypertransaminasaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: Alopecia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermal cyst	Additional description: Dermal cyst		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Erythema	Additional description: Erythema		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nail disorder	Additional description: Nail disorder		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Night sweats	Additional description: Night sweats		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	Additional description: Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: Photosensitivity reaction		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0

Rash	Additional description: Rash		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: Seborrhoeic dermatitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Sensitive skin	Additional description: Sensitive skin		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation	Additional description: Skin exfoliation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Xanthelasma	Additional description: Xanthelasma		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 20 (0.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Genitourinary symptom	Additional description: Genitourinary symptom		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia	Additional description: Nocturia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Proteinuria	Additional description: Proteinuria		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal impairment	Additional description: Renal impairment		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased	Additional description: Urine flow decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid	Additional description: Cushingoid		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Glucocorticoid deficiency	Additional description: Glucocorticoid deficiency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaldosteronism	Additional description: Hypoaldosteronism		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Bone pain	Additional description: Bone pain		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain	Additional description: Flank pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression	Additional description: Intervertebral disc compression		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness	Additional description: Joint stiffness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: Joint swelling		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain	Additional description: Neck pain		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sacral pain	Additional description: Sacral pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess jaw	Additional description: Abscess jaw		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Candida infection	Additional description: Candida infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye infection	Additional description: Eye infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection	Additional description: Fungal foot infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Infection	Additional description: Infection		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Influenza	Additional description: Influenza		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	1	1	2
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis	Additional description: Nasal vestibulitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Periorbital cellulitis	Additional description: Periorbital cellulitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 20 (5.00%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	3 / 20 (15.00%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	2	2
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired	Additional description: Glucose tolerance impaired		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia	Additional description: Hypervolaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia	Additional description: Hypochloraemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 20 (5.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	4	0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Hypophagia	Additional description: Hypophagia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B2 deficiency	Additional description: Vitamin B2 deficiency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 May 2018	Section 1.6, Section 6.4 and Section 6.6.5 were amended to include monitoring of luteinising hormone, follicle stimulating hormone and testosterone; Section 1.6, Section 4.1, Section 6.4 and Section 6.6.5 were amended to clarify serum pregnancy test at screening; Section 4.2, Criteria 1, Section 4.3.3 and Appendix E were amended to clarify abiraterone, enzalutamide and CYP3A4 inducer/inhibitor washout timings; Section 4.3.1 were amended to clarify contraception requirements; Section 4.3.2 was added to include sperm and egg donation restrictions; Section 5.2 was amended to clarify dosing of parallel cohorts; Section 5.7.1 was amended to clarify dose modifications.
11 February 2019	Section 4 text made aligned to clarify eligibility performed at screening (as per Study plan); Section 4.1 Criterion 5 amended to utilise Cockcroft-Gault formula. Also amended to include information for patients with Gilbert's syndrome; Section 4.1 Criterion 18 amended to clarify patient population for Part E, Section 4.1 Criterion 19, Section 5.6, Study Plan, Section 6.3 and Section 6.10.2 amended to state that p300/CBP mutation would be identified from FFPE tumour biopsy samples using the FoundationOne CDx™ test; Section 4.2 Criterion 6 amended to state QTcF prolongation to >480 ms; Section 4.2 Criterion 8 amended to allow entry of patients with stable brain metastases; Section 4.3.3 Clarification that only the first subsequent anti-cancer treatment would be collected; Section 4.3.3 Clarification of treatment of anaemia and thrombocytopenia; Section 5.1.1 Clarification of allowable dosing window for intermittent dosing; Section 5.1.3 and Section 5.5 amended to allow starting dose of enzalutamide to be lower than the recommended dose due to potential DDIs; Section 5.2.1 provision for potential quadrupling of dose removed; Section 5.2.2 DLT criteria expanded to provide further clarity on DLTs; Section 6.1, Study Plan and Section 6.8.1 updated to provide details regarding PK steady state profiles to be taken in Cycle 1 and 2 and to provide information for intermittent schedules; Study Plan and Section 6.11 clarification added that overall survival should be assessed every 12 weeks; Section 6.6.4, addition of ECGs at 2 hours post dose on C1D1 and Day 15; Section 6.6.5 clarification that blood urea nitrogen or urea should be assessed, and to include anti-coagulation testing at each sampling time point, not only at screening; Section 6.7 clarification that CTCAE v5.0 should be used; Section 6.7.3 confirmation that only related AEs need to be follow up if ongoing at the EOS; Section 6.7.4 clarification of SAE reporting; Section 6.8.3 PK urine removed from Part A.

30 January 2020	Sections 1.3, 1.6.3, 1.7, 2, 3.2, 4.1, 5.6, Figure 2 Part E amended to include patients with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition.; Section 1.6.5 added rationale for transition from current CCS1477 composition to modified CCS1477 composition; Section 2, 5.3, Figure 2, updated to include 2 potential monotherapy expansion arms in mCRPC; Section 2, Figure 2 updated to include Part E1 to allow patients with advanced solid tumours with molecular markers which may indicate potential for response to p300/CBP inhibition to be entered into the study during the escalation phase; Section 4.2 exclusion 1 updated to clarify the restrictions regarding prohibited medications prior to and during the study; Section 5.2.6 added to include information regarding the switch from the current CCS1477 composition to the modified CCS1477 composition; Section 5.3.1 Food effect cohort included; Section 6.5.4 and study plan updated to move ECG from Day 15 to Day 8 to coincide with PK sampling, and to remove collection of P-wave duration; Section 6.3 and Study Plan updated to remove biopsy sample for mutation testing; Section 6.5.5 updated to include CRP in laboratory measurements; Section 6.5.6 updated to include additional monitoring for patients with moderate hepatic impairment who are receiving abiraterone; Section 6.7.2 and Study plan updated to include urine PK in Part A and change PK urine sample from Day 15/16 to Day 8/9 of cycle 1; Section 6.8.4 and Study plan added tumour biomarker sampling for non-mCRPC patients; Section 6.9.2 and Study Plan updated to include further blood samples for exploratory biomarkers; Section 6.9.4 updated to include progression biopsy; Section 6.10 updated to amend window for follow-up visit.
27 July 2020	Section 4.1 Inclusion criteria 17 updated to include information for DDI arm; Section 4.1 Inclusion criteria 19 updated to include further information regarding selection of patients for Part E; Section 4.2 Exclusion criteria 1 updated to include information for DDI arm; Section 4.3.3 updated to clarify washouts; Sections 5.1.3, 5.5, Table 1, 6.1, 6.4, 7.8 updated to provide details of DDI arm; Section 5.2.1 inclusion of PK sampling following intra-patient dose escalation; Section 5.2.2 clarification of DLT period for Part D1; Section 5.6 clarification around patient numbers for Part E1; Sections 5.7.3, 5.7.4, 6.6.4, Appendix F and Appendix G clarification of RSI and safety information for abiraterone and enzalutamide; Sections 6.3 and 6.4 updated to visit and assessment requirements during abiraterone and enzalutamide run-in period; Section 6.5.4 HR included; Section 6.6.3 AE recording clarified; Section 6.7.1 clarification of PK sampling timepoints; Section 6.8.1 clarification of CT/MRI scan timing; Section 6.9 clarification of timings for biomarker samples; Section 9.1 Study timelines updated.
25 March 2022	Synopsis and Sections 1.6.4, 1.6.5, 1.6.6, 1.6.8, 2, 3, 5, 6 updated to include new combination arms; Section 1.7 potential risks updated for CCS1477 and combination agents; Section 4.1 and 4.2 Inclusion and exclusion criteria updated, and further criteria updated for combination agents; Section 4.3 Contraception restrictions updated; Sections 5.10.1 – 5.10.8 updated to include management of combination agent related AEs and clarification of stopping rules; Section 6.2 consent period clarified; Section 6.5.5 addition of further safety laboratory assessments; Section 6.5.7 added to include general monitoring for patients on atezolizumab; Section 6.6.3 clarification of relationship definition; Section 6.7.1 addition of PK sampling details for combination arms; Section 7 statistical aspects updated in line with addition of new combination arms; Section 9.1 study timelines updated; Section 10 overdose details included for combination agents.
12 May 2022	Inclusion Criteria 22 was updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported