



Clinical trial results:

Phase 1/2 Study of TAS-120 in Patients With Advanced Solid Tumors Harboring FGF/FGFR Aberrations

Summary

EudraCT number	2013-004810-16
Trial protocol	GB ES DE NL PT
Global end of trial date	22 October 2024

Results information

Result version number	v1 (current)
This version publication date	02 November 2025
First version publication date	02 November 2025

Trial information

Trial identification

Sponsor protocol code	TPU-TAS-120-101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02052778
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Taiho Oncology, Inc.
Sponsor organisation address	101 Carnegie Center, Suite 101, Princeton, New Jersey, United States, 08540
Public contact	Senior Study Manager, Taiho Oncology, Inc, +1 844-878-2446, medicalinformation@taihooncology.com
Scientific contact	Senior Study Manager, Taiho Oncology, Inc., +1 844-878-2446, medicalinformation@taihooncology.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	29 May 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	22 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the trial were:

Phase 1 Dose Escalation: to determine the maximum tolerated dose (MTD) and/or Recommended Phase 2 dose (RP2D) of TAS-120.

Phase 1 Expansion: to further evaluate the efficacy and safety of the MTD and/or RP2D of TAS-120 in subjects with tumors harboring specific Fibroblast growth factor/ Fibroblast growth factor receptor (FGF/FGFR) aberrations.

Phase 2: to confirm the Objective Response Rate (ORR) of TAS-120 in Intra-hepatic cholangiocarcinoma (iCCA) patients with tumors harboring FGFR2 gene fusions or other FGFR2 rearrangements.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 July 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Australia: 16
Country: Number of subjects enrolled	Korea, Republic of: 19
Country: Number of subjects enrolled	United States: 166
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Japan: 14
Country: Number of subjects enrolled	Taiwan: 6
Country: Number of subjects enrolled	Hong Kong: 1
Country: Number of subjects enrolled	Spain: 42
Country: Number of subjects enrolled	United Kingdom: 46
Country: Number of subjects enrolled	France: 69
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Italy: 2
Worldwide total number of subjects	386
EEA total number of subjects	117

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)	290
From 65 to 84 years	96
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study had Phase 1 and 2. Phase 1: Dose Escalation: 86 treated and Dose Expansion: 197 treated; Phase 2: 103 treated.

For Subject Disposition, Baseline characteristics, and Adverse Events, QOD and QD dosing were combined for Phase 1 Dose Escalation as pre-planned in protocol.

Pre-assignment

Screening details:

Phase 1 Dose Expansion sub-cohorts 1&2: efficacy data presented at 30-Jun-2019 cut-off as all subjects had disease progression or had discontinued. Primary analysis (PFS&OS) data were presented as pre planned in protocol at this cut-off. Phase 1 Expansion & Phase 2, subjects with clinical benefit had efficacy data presented at 29-May-2021 cut-off.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1: Dose Escalation: QOD Dosing: 8 mg

Arm description:

Subjects with or without fibroblast growth factor [FGF]/fibroblast growth factor receptor [FGFR] gene abnormalities received TAS-120 8 milligrams (mg) orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 16 mg
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Arm description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 16 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 24 mg
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Arm description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 24 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 36 mg
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Arm description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 36 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Capsule, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 56 mg
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Arm description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 56 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Capsule, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 80 mg
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Arm description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 80 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week)

in a 21-day treatment cycle.

Arm title	Phase 1: Dose Escalation: QOD Dosing: 120 mg
Arm description: Subjects with FGF/FGFR gene abnormalities received TAS-120 120 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QOD Dosing: 160 mg
Arm description: Subjects with FGF/FGFR gene abnormalities received TAS-120 160 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Arm description: Subjects with FGF/FGFR gene abnormalities received TAS-120 200 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: TAS-120 was administered orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: (Once Daily) QD Dosing: 4 mg
Arm description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 4 mg orally once daily (QD) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental

Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 4 mg was administered orally once daily (QD) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QD Dosing: 8 mg
Arm description:	
Subjects with or without FGF/FGFR gene abnormalities received a dose between 8 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 8 mg was administered orally once daily (QD) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QD Dosing: 16 mg
Arm description:	
Subjects with or without FGF/FGFR gene abnormalities received a dose between 16 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 16 mg was administered orally once daily (QD) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QD Dosing: 20 mg
Arm description:	
Subjects with or without FGF/FGFR gene abnormalities received a dose between 20 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg was administered orally once daily (QD) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Escalation: QD Dosing: 24 mg
Arm description:	
Subjects with or without FGF/FGFR gene abnormalities received a dose between 24 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental

Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 24 mg was administered orally once daily (QD) in a 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion Cohort 1
Arm description:	
Subjects with intra-hepatic or extrahepatic cholangiocarcinoma (iCCA or eCCA) harboring FGFR2 gene fusions or rearrangements and who were treated or not treated with prior FGFR inhibitors received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Cohort 2
Arm description:	
Subjects with primary central nervous system (CNS) tumors harboring FGFR gene fusions or FGFR1 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Cohort 3
Arm description:	
Subjects with advanced urothelial carcinoma harboring FGFR3 gene fusions or FGFR3 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Cohort 4
Arm description:	
Subjects with breast or gastric cancer with harboring FGFR2 amplification received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental

Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Cohort 5
Arm description:	
Subjects with tumor types harboring FGFR gene fusions or activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Cohort 6
Arm description:	
Subjects who were not included in Cohorts 1 to 5 received TAS-120 20 mg tablets orally QD in each of 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 20 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Sub-cohort 1
Arm description:	
Subjects with iCCA who were enrolled prior to the confirmation of the recommended Phase 2 dose (RP2D) received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 16 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 1: Dose Expansion: Sub-cohort 2
Arm description:	
Subjects with other tumor types who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Arm type	Experimental

Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
TAS-120 16 mg tablets were administered orally daily QD in each of 21-day treatment cycle.	
Arm title	Phase 2

Arm description:

Subjects with iCCA with tumors harboring FGFR2 gene rearrangements received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

TAS-120 20 mg tablets were administered orally daily QD in each of 21-day treatment cycle.

Number of subjects in period 1	Phase 1: Dose Escalation: QOD Dosing: 8 mg	Phase 1: Dose Escalation: QOD Dosing: 16 mg	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Started	6	3	3
Completed	0	0	0
Not completed	6	3	3
Adverse Event	-	-	-
Death	-	-	-
Clinical disease progression	2	1	1
Radiographic progression	-	2	-
Investigator decision	-	-	-
Radiographic progression	4	-	2
Unspecified	-	-	-
Withdrawal by subject	-	-	-

Number of subjects in period 1	Phase 1: Dose Escalation: QOD Dosing: 36 mg	Phase 1: Dose Escalation: QOD Dosing: 56 mg	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Started	3	3	5
Completed	0	0	0
Not completed	3	3	5
Adverse Event	-	-	-
Death	-	-	-
Clinical disease progression	2	1	1
Radiographic progression	-	-	-

Investigator decision	-	-	1
Radiographic progression	1	2	3
Unspecified	-	-	-
Withdrawal by subject	-	-	-

Number of subjects in period 1	Phase 1: Dose Escalation: QOD Dosing: 120 mg	Phase 1: Dose Escalation: QOD Dosing: 160 mg	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Started	4	8	7
Completed	0	0	0
Not completed	4	8	7
Adverse Event	-	-	-
Death	1	-	-
Clinical disease progression	3	2	1
Radiographic progression	-	-	-
Investigator decision	-	-	-
Radiographic progression	-	6	5
Unspecified	-	-	-
Withdrawal by subject	-	-	1

Number of subjects in period 1	Phase 1: Dose Escalation: (Once Daily) QD Dosing: 4 mg	Phase 1: Dose Escalation: QD Dosing: 8 mg	Phase 1: Dose Escalation: QD Dosing: 16 mg
Started	4	5	14
Completed	0	0	0
Not completed	4	5	14
Adverse Event	-	-	-
Death	-	-	1
Clinical disease progression	-	-	2
Radiographic progression	-	-	-
Investigator decision	-	-	-
Radiographic progression	4	5	11
Unspecified	-	-	-
Withdrawal by subject	-	-	-

Number of subjects in period 1	Phase 1: Dose Escalation: QD Dosing: 20 mg	Phase 1: Dose Escalation: QD Dosing: 24 mg	Phase 1: Dose Expansion Cohort 1
Started	7	14	57
Completed	0	0	0
Not completed	7	14	57
Adverse Event	-	1	5
Death	-	-	-
Clinical disease progression	2	3	6
Radiographic progression	-	-	-

Investigator decision	1	-	5
Radiographic progression	4	7	38
Unspecified	-	-	1
Withdrawal by subject	-	3	2

Number of subjects in period 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Started	34	15	13
Completed	0	0	0
Not completed	34	15	13
Adverse Event	1	3	-
Death	-	-	-
Clinical disease progression	3	-	2
Radiographic progression	-	-	-
Investigator decision	3	-	-
Radiographic progression	23	12	11
Unspecified	1	-	-
Withdrawal by subject	3	-	-

Number of subjects in period 1	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Sub-cohort 1
Started	24	27	19
Completed	0	0	0
Not completed	24	27	19
Adverse Event	3	1	-
Death	-	-	-
Clinical disease progression	3	4	5
Radiographic progression	-	-	-
Investigator decision	-	1	-
Radiographic progression	17	21	14
Unspecified	1	-	-
Withdrawal by subject	-	-	-

Number of subjects in period 1	Phase 1: Dose Expansion: Sub-cohort 2	Phase 2
Started	8	103
Completed	0	0
Not completed	8	103
Adverse Event	-	7
Death	-	-
Clinical disease progression	1	6
Radiographic progression	-	-
Investigator decision	-	3

Radiographic progression	6	78
Unspecified	1	7
Withdrawal by subject	-	2

Baseline characteristics

Reporting groups

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 8 mg
Reporting group description: Subjects with or without fibroblast growth factor [FGF]/fibroblast growth factor receptor [FGFR] gene abnormalities received TAS-120 8 milligrams (mg) orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 16 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 16 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 24 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 36 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 36 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 56 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 56 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 80 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 120 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 120 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 160 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 160 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 200 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: (Once Daily) QD Dosing: 4 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 4 mg orally once daily (QD) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 8 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 8 mg orally QD in a 21-	

day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 16 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 16 mg orally QD in a 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 20 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 20 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 24 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 24 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion Cohort 1
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Reporting group description:

Subjects with intra-hepatic or extrahepatic cholangiocarcinoma (iCCA or eCCA) harboring FGFR2 gene fusions or rearrangements and who were treated or not treated with prior FGFR inhibitors received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 2
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Reporting group description:

Subjects with primary central nervous system (CNS) tumors harboring FGFR gene fusions or FGFR1 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 3
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Reporting group description:

Subjects with advanced urothelial carcinoma harboring FGFR3 gene fusions or FGFR3 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 4
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Reporting group description:

Subjects with breast or gastric cancer with harboring FGFR2 amplification received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 5
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Reporting group description:

Subjects with tumor types harboring FGFR gene fusions or activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 6
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Reporting group description:

Subjects who were not included in Cohorts 1 to 5 received TAS-120 20 mg tablets orally QD in each of 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Sub-cohort 1
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Reporting group description:

Subjects with iCCA who were enrolled prior to the confirmation of the recommended Phase 2 dose (RP2D) received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Sub-cohort 2
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Reporting group description:

Subjects with other tumor types who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 2
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Reporting group description:

Subjects with iCCA with tumors harboring FGFR2 gene rearrangements received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group values	Phase 1: Dose Escalation: QOD Dosing: 8 mg	Phase 1: Dose Escalation: QOD Dosing: 16 mg	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Number of subjects	6	3	3
Age categorical			
Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	4	2	2
>/=65 years	2	1	1
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	4	1	2
Male	2	2	1
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	2	3
Unknown or Not Reported	0	1	0
Race/Ethnicity			
Units: Subjects			
Asian/Oriental	0	0	0
White/Caucasian	6	3	3
Black or African-American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	0	0	0

Reporting group values	Phase 1: Dose Escalation: QOD Dosing: 36 mg	Phase 1: Dose Escalation: QOD Dosing: 56 mg	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Number of subjects	3	3	5
Age categorical			
Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	2	2	3
>/=65 years	1	1	2
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	2	0	4
Male	1	3	1
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	2
Unknown or Not Reported	1	1	3
Race/Ethnicity			
Units: Subjects			

Asian/Oriental	0	0	0
White/Caucasian	3	2	1
Black or African-American	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	0	1	3

Reporting group values	Phase 1: Dose Escalation: QOD Dosing: 120 mg	Phase 1: Dose Escalation: QOD Dosing: 160 mg	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Number of subjects	4	8	7
Age categorical Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	1	6	5
>/=65 years	3	2	2
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	1	4	5
Male	3	4	2
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	3
Unknown or Not Reported	1	5	4
Race/Ethnicity Units: Subjects			
Asian/Oriental	0	0	0
White/Caucasian	3	5	5
Black or African-American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	1	3	2

Reporting group values	Phase 1: Dose Escalation: (Once Daily) QD Dosing: 4 mg	Phase 1: Dose Escalation: QD Dosing: 8 mg	Phase 1: Dose Escalation: QD Dosing: 16 mg
Number of subjects	4	5	14
Age categorical Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	3	3	12
>/=65 years	1	2	2
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	2	0	8
Male	2	5	6
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			

Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	7
Unknown or Not Reported	2	2	7
Race/Ethnicity Units: Subjects			
Asian/Oriental	0	0	0
White/Caucasian	3	4	7
Black or African-American	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	1	0	7

Reporting group values	Phase 1: Dose Escalation: QD Dosing: 20 mg	Phase 1: Dose Escalation: QD Dosing: 24 mg	Phase 1: Dose Expansion Cohort 1
Number of subjects	7	14	57
Age categorical Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	4	11	45
>/=65 years	3	3	12
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	6	13	40
Male	1	1	17
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	1	2
Not Hispanic or Latino	6	6	41
Unknown or Not Reported	1	7	14
Race/Ethnicity Units: Subjects			
Asian/Oriental	1	2	6
White/Caucasian	6	8	37
Black or African-American	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	0	4	13

Reporting group values	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Number of subjects	34	15	13
Age categorical Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	27	5	10
>/=65 years	7	10	3
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	12	4	9

Male	22	11	4
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Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	19	7	13
Unknown or Not Reported	15	8	0
Race/Ethnicity			
Units: Subjects			
Asian/Oriental	2	0	8
White/Caucasian	17	7	2
Black or African-American	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	1
Missing/Unknown	15	8	0

Reporting group values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Sub-cohort 1
Number of subjects	24	27	19
Age categorical			
Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	21	18	18
>/=65 years	3	9	1
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	14	16	14
Male	10	11	5
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	16	23	18
Unknown or Not Reported	8	3	0
Race/Ethnicity			
Units: Subjects			
Asian/Oriental	3	2	1
White/Caucasian	15	22	16
Black or African-American	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Missing/Unknown	6	2	1

Reporting group values	Phase 1: Dose Expansion: Sub-cohort 2	Phase 2	Total
Number of subjects	8	103	386

Age categorical			
Units: Subjects			
</=18 years	0	0	0
Between 18 and 65 years	6	80	290
>/=65 years	2	23	96
Gender categorical			
Analysis was performed on all treated population.			
Units: Subjects			
Female	7	58	226
Male	1	45	160
Ethnicity (NIH/OMB)			
Analysis was performed on all treated population.			
Units: Subjects			
Hispanic or Latino	2	2	9
Not Hispanic or Latino	5	89	281
Unknown or Not Reported	1	12	96
Race/Ethnicity			
Units: Subjects			
Asian/Oriental	0	30	55
White/Caucasian	7	51	233
Black or African-American	0	8	15
Native Hawaiian or Other Pacific Islander	0	1	2
Missing/Unknown	1	13	81

End points

End points reporting groups

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 8 mg
Reporting group description: Subjects with or without fibroblast growth factor [FGF]/fibroblast growth factor receptor [FGFR] gene abnormalities received TAS-120 8 milligrams (mg) orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 16 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 16 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 24 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 36 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received TAS-120 36 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 56 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 56 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 80 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 120 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 120 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 160 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 160 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 200 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: (Once Daily) QD Dosing: 4 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 4 mg orally once daily (QD) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 8 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 8 mg orally QD in a 21-	

day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 16 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 16 mg orally QD in a 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 20 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 20 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QD Dosing: 24 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received a dose between 24 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion Cohort 1
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Reporting group description:

Subjects with intra-hepatic or extrahepatic cholangiocarcinoma (iCCA or eCCA) harboring FGFR2 gene fusions or rearrangements and who were treated or not treated with prior FGFR inhibitors received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 2
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Reporting group description:

Subjects with primary central nervous system (CNS) tumors harboring FGFR gene fusions or FGFR1 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 3
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Reporting group description:

Subjects with advanced urothelial carcinoma harboring FGFR3 gene fusions or FGFR3 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 4
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Reporting group description:

Subjects with breast or gastric cancer with harboring FGFR2 amplification received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 5
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Reporting group description:

Subjects with tumor types harboring FGFR gene fusions or activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Cohort 6
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Reporting group description:

Subjects who were not included in Cohorts 1 to 5 received TAS-120 20 mg tablets orally QD in each of 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Sub-cohort 1
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Reporting group description:

Subjects with iCCA who were enrolled prior to the confirmation of the recommended Phase 2 dose (RP2D) received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Expansion: Sub-cohort 2
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Reporting group description:

Subjects with other tumor types who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 2
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Reporting group description:

Subjects with iCCA with tumors harboring FGFR2 gene rearrangements received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Subject analysis set title	Phase 1: Dose Escalation: QOD Dosing
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects with or without FGF/FGFR gene abnormalities received TAS-120 at 4 DLs from 8 to 36 mg orally every other day (QOD; Monday, Wednesday and Friday of each week) and subjects with FGF/FGFR abnormalities received TAS-120 at 6 DLs from 56 mg to 240 mg orally QOD in a 21-day treatment cycle until disease progression, unacceptable toxicity, or any other discontinuation criterion was met (maximum exposure: 11 months).	
Subject analysis set title	Phase 1: Dose Escalation: QD Dosing
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects with or without FGF/FGFR gene abnormalities received a dose between 4 to 24 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, or any other discontinuation criterion was met (maximum exposure: 24 months).	
Subject analysis set title	Phase 1: Dose Expansion: Pooled Sub-cohort
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects with iCCA and other tumor types who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21- day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	

Primary: Phase 1: Dose Escalation- MTD

End point title	Phase 1: Dose Escalation- MTD ^[1]
End point description:	
MTD: highest dose with <33% DLTs in Cycle 1. DLTs: ≥G3 nonhematologic toxicity; nausea/vomiting >48h despite antiemetics; diarrhea >48h despite antidiarrheals; G4 neutropenia >7d; febrile neutropenia (ANC<1000 & fever ≥38.3°C or ≥38°C >1h); G4/G3 thrombocytopenia with bleeding or transfusion; corneal disorder worsened ≥1 grade; phosphorus ≥9 mg/dL or ≥7 mg/dL ≥7d or requiring phosphate-lowering therapy (PLT) 7d; creatinine >1.5×ULN ≥7d with phosphorus >5.5 mg/dL (PLT 7d) or Ca×P >55 mg/dL (PLT 7d); hypercalcemia G2 >7d or G3; ectopic soft tissue calcification; >G2 toxicities preventing Cycle 1 completion or Cycle 2 start within 2 weeks. '9999'-MTD for QOD dosing was not determined as no DLTs were observed for TAS-120 up to 200 mg QOD as the highest dose level studied. DLT evaluable population-all subjects in Phase 1 Dose Escalation who had either experience a DLT during the first cycle of treatment or who had completed the first cycle with at least 80% of planned TAS-120 administered.	
End point type	Primary
End point timeframe:	
Cycle 1 (21-day cycle).	

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: Only descriptive statistics is provided for this end point.

End point values	Phase 1: Dose Escalation: QOD Dosing	Phase 1: Dose Escalation: QD Dosing		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	44		
Units: milligrams				
number (not applicable)	9999	20		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose Escalation- RP2D of TAS-120

End point title	Phase 1: Dose Escalation- RP2D of TAS-120 ^[2]
End point description: RP2D was MTD or lower. MTD: highest dose with <33% DLTs in Cycle 1. DLTs: ≥G3 nonhematologic toxicity; nausea/vomiting >48h despite antiemetics; diarrhea >48h despite antidiarrheals; G4 neutropenia >7d; febrile neutropenia (ANC<1000 & fever ≥38.3°C or ≥38°C >1h); G4/G3 thrombocytopenia with bleeding or transfusion; corneal disorder worsened ≥1 grade; phosphorus ≥9 mg/dL or ≥7 mg/dL ≥7d or requiring PLT 7d; creatinine >1.5×ULN ≥7d with phosphorus >5.5 mg/dL (PLT 7d) or Ca×P >55 mg/dL (PLT 7d); hypercalcemia G2 >7d or G3; ectopic soft tissue calcification; >G2 toxicities preventing Cycle 1 completion or Cycle 2 start within 2 weeks. '9999'-MTD for QOD dosing was not determined as no DLTs were observed for TAS-120 up to 200 mg QOD as the highest dose level studied and thus no RP2D was determined. DLT evaluable population.	
End point type	Primary
End point timeframe: Cycle 1 (21-day cycle)	
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: Only descriptive statistics is provided for this end point.	

End point values	Phase 1: Dose Escalation: QOD Dosing	Phase 1: Dose Escalation: QD Dosing		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	44		
Units: milligrams				
number (not applicable)	9999	20		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose Expansion: Percentage of Subjects With Objective Response

End point title	Phase 1: Dose Expansion: Percentage of Subjects With Objective Response ^{[3][4]}
End point description: Objective response was defined as proportion of subjects who had achieved best overall response of partial response (PR) or complete response (CR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. The CR was defined as a disappearance of all target lesions. Any pathological lymph nodes (target or non-target) must had reduction in short axis to <10 millimeters (mm) and PR was defined as at least a 30 percent (%) decrease in the sum of diameters of target lesions. For Cohorts 1 to 6: Objective response was based on Independent Review Committee (IRC) and for pooled Sub-cohort: Objective response was based on investigator review. Efficacy population included all subjects who had received at least 1 dose of TAS-120. Data was planned to be collected and analysed on pooled population of subjects who received 16 mg of TAS-120 in the sub-cohorts 1and 2.	
End point type	Primary
End point timeframe: Up to approximately 50.5 months (through cut-off date 29-May-2021) for Cohorts 1 to 6; up to approximately 27.5 months (through cut-off date 30-Jun-2019) for pooled sub-cohorts.	
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: Only descriptive statistics is provided for this end point. [4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in	

End point values	Phase 1: Dose Expansion Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	34	15	13
Units: Percentage of subjects				
number (confidence interval 95%)	15.8 (7.5 to 27.9)	8.8 (1.9 to 23.7)	13.3 (1.7 to 40.5)	0 (0.0 to 24.7)

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Pooled Sub-cohort	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	24	27	27	
Units: Percentage of subjects				
number (confidence interval 95%)	12.5 (2.7 to 32.4)	0 (0.0 to 12.8)	33.3 (16.5 to 54.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Percentage of Subjects With Objective Response

End point title	Phase 2: Percentage of Subjects With Objective Response ^{[5][6]}
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End point description:

Objective response was defined as proportion of subjects who had achieved best overall response of PR or CR per RECIST v1.1. CR was defined as a disappearance of all target lesions. Any pathological lymph nodes (target or non-target) must had reduction in short axis to <10 mm and PR was defined as at least a 30% decrease in the sum of diameters of target lesions. The Phase 2 evaluation of objective response was based on central independent CT/MRI image assessment. Efficacy population included all treated iCCA subjects with confirmed FGFR2 gene fusions or other FGFR2 rearrangements who had received at least 1 dose of TAS-120

End point type	Primary
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End point timeframe:

Up to approximately 37.5 months (through cut-off date 29-May-2021)

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: Only descriptive statistics is provided for this end point.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: Percentage of subjects				
number (confidence interval 95%)	41.7 (32.1 to 51.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Dose Expansion: Duration of Response (DOR)

End point title	Phase 1: Dose Expansion: Duration of Response (DOR) ^[7]
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End point description:

A DOR was defined as the time (in months) from the first documentation of response (CR or PR) to the first documentation of objective progressive disease (PD) or death due to any cause, whichever occurred first. Subjects who started subsequent anticancer therapy without a prior reported progression were censored at the last tumor assessments prior to initiation of the subsequent anticancer therapy. For Cohorts 1 to 6: DOR was based on IRC and for Group 3, 4, 5, 6 and for pooled Sub-cohort: DOR was based on investigator review. Analysis was performed on the subset of subjects with PR or CR in efficacy population. Here, 'number of subjects analysed' signifies subjects with available data for this outcome measure. Data was planned to be collected and analysed on pooled population of subjects who received 16 mg of TAS-120 in the sub-cohorts 1 and 2.

End point type	Secondary
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End point timeframe:

Up to approximately 50.5 months (through cut-off date 29-May-2021) for Cohorts 1 to 6; up to approximately 27.5 months (through cut-off date 30-Jun-2019) for pooled sub-cohorts.

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in Protocol and SAP.

End point values	Phase 1: Dose Expansion: Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	2	2	0 ^[8]
Units: months				
median (full range (min-max))	6.18 (2.8 to 10.6)	3.52 (2.8 to 4.3)	2.45 (1.4 to 3.4)	(to)

Notes:

[8] - No subject had an event

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Pooled Sub-cohort	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	3	0 ^[9]	9	
Units: months				
median (full range (min-max))	2.79 (2.0 to 4.1)	(to)	8.77 (3.5 to 20.8)	

Notes:

[9] - No subject had an event

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of Response (DOR)

End point title	Phase 2: Duration of Response (DOR) ^[10]
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End point description:

A DOR was defined as the time (in months) from the first documentation of response (CR or PR) to the first documentation of objective tumor progression or death due to any cause, whichever occurred first. Subjects who started subsequent anticancer therapy without a prior reported progression were censored at the last tumor assessments prior to initiation of the subsequent anticancer therapy. Analysis was performed on the subset of subjects with PR or CR in efficacy population. Here, 'number of subjects analysed' signifies subjects with available data for this outcome measure.

End point type	Secondary
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End point timeframe:

Up to approximately 37.5 months (through cut-off date 29-May-2021).

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: months				
median (full range (min-max))	8.31 (2.1 to 24.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Dose Expansion: Disease Control Rate (DCR)

End point title	Phase 1: Dose Expansion: Disease Control Rate (DCR) ^[11]
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End point description:

DCR was defined as the proportion of subjects with CR, PR, or SD lasting ≥ 6 weeks after treatment start (no SD confirmation required). CR: disappearance of all target lesions, with lymph nodes < 10 mm. PR: $\geq 30\%$ decrease in sum of target lesion diameters from baseline. SD: neither sufficient shrinkage for PR nor increase for PD, using the smallest on-study sum as reference. For Cohorts 1–6, DCR was per IRC; for pooled sub-cohort, by investigator. Efficacy population included all subjects who had received at least 1 dose of TAS-120. Data was planned to be collected and analysed on pooled population of subjects who received 16 mg of TAS-120 in the sub-cohorts 1 and 2.

End point type	Secondary
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End point timeframe:

Up to approximately 50.5 months (through cut-off date 29-May-2021) for Cohorts 1 to 6; up to

approximately 27.5 months (through cut-off date 30-Jun-2019) for pooled sub-cohort.

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in Protocol and SAP.

End point values	Phase 1: Dose Expansion Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	34	15	13
Units: Percentage of subjects				
number (confidence interval 95%)	66.7 (52.9 to 78.6)	23.5 (10.7 to 41.2)	33.3 (11.8 to 61.6)	38.5 (13.9 to 68.4)

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Pooled Sub-cohort	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	24	27	27	
Units: Percentage of subjects				
number (confidence interval 95%)	54.2 (32.8 to 74.4)	22.2 (8.6 to 42.3)	66.7 (46.0 to 83.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Disease Control Rate (DCR)

End point title	Phase 2: Disease Control Rate (DCR) ^[12]
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End point description:

A DCR was defined as the proportion of subjects with objective evidence of CR, PR, or SD, except that there was no requirement for a confirmation of an SD response, if it is maintained for at least 6 weeks post treatment initiation. CR was defined as the disappearance of all target lesions. Any pathological lymph nodes might had reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the Baseline sum diameters. SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taken as a reference the smallest sum diameters while on study. DCR was based on IRC. Efficacy population included all treated iCCA subjects with confirmed FGFR2 gene fusions or other FGFR2 rearrangements who had received at least 1 dose of TAS-120.

End point type	Secondary
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End point timeframe:

Up to approximately 37.5 months (through cut-off date 29-May-2021)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: Percentage of subjects				
number (confidence interval 95%)	82.5 (73.8 to 89.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Dose Expansion: Progression-free Survival (PFS)

End point title	Phase 1: Dose Expansion: Progression-free Survival (PFS) ^[13]
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End point description:

PFS was defined as the time (months) from first dose to disease progression or death (any cause), whichever came first. Subjects who died without documented progression were considered progressed at death. Those without progression or death were censored at last tumor assessment; those with no on-study assessment and alive were censored at first dose; and those starting new anti-cancer therapy before progression were censored at last assessment before new therapy. PFS was assessed by IRC for Cohorts 1–6 and by investigator for pooled sub-cohort. Efficacy population included all subjects who had received at least 1 dose of TAS-120. Data was planned to be collected and analysed on pooled population of subjects who received 16 mg of TAS-120 in the sub-cohorts 1 and 2.

End point type	Secondary
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End point timeframe:

Up to approximately 27.5 months (through cut-off date 30-Jun-2019).

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in Protocol and SAP.

End point values	Phase 1: Dose Expansion Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	34	15	13
Units: months				
median (confidence interval 95%)	4.1 (2.7 to 6.9)	1.9 (1.3 to 4.9)	1.8 (1.3 to 4.7)	1.3 (0.9 to 4.1)

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Pooled Sub-cohort	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	24	27	27	
Units: months				
median (confidence interval 95%)	3.5 (1.7 to 6.8)	2.7 (1.4 to 2.7)	6.9 (4.6 to 10.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Progression-free Survival (PFS)

End point title	Phase 2: Progression-free Survival (PFS) ^[14]
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End point description:

A PFS was defined as the time (in months) from the day of the first dose to the date of first objectively documented disease progression or death (any cause), whichever occurred first. Subjects who had died without a reported disease progression were considered to have progressed on the date of their death, subjects who did not progress or die were censored on the date of their last tumor assessment, subjects who had no on-study assessments and did not die were censored on the first dosing date, and subjects who started any subsequent anti-cancer therapy without a prior reported progression were censored at the last tumor assessment prior to initiation of the subsequent anti-cancer therapy. PFS was analysed as using Kaplan-Meier estimate. Efficacy population included all treated iCCA subjects with confirmed FGFR2 gene fusions or other FGFR2 rearrangements who had received at least 1 dose of TAS-120.

End point type	Secondary
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End point timeframe:

Up to approximately 37.5 months (through cut-off date 29-May-2021).

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: months				
median (confidence interval 95%)	8.9 (6.7 to 11.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Dose Expansion: Overall Survival (OS)

End point title	Phase 1: Dose Expansion: Overall Survival (OS) ^[15]
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End point description:

An OS was defined as the time (in months) from the date of the first dose to the death date. In the absence of death confirmation or for subjects alive as of the OS cut-off date, survival time was censored at the date of last study follow-up, or the cut-off date, whichever was earlier. '9999' signifies that upper limit of 95% confidence interval (CI) was not estimable due to the smaller number of subjects with events. '999' signifies that median was not estimable due to the smaller number of subjects with events. Efficacy population included all subjects who had received at least 1 dose of TAS-120. Data was planned to be collected and analysed on pooled population of subjects who received 16 mg of TAS-120 in the sub-cohorts 1 and 2.

End point type	Secondary
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End point timeframe:

Up to approximately 27.5 months (through cut-off date 30-Jun-2019).

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in Protocol and SAP.

End point values	Phase 1: Dose Expansion Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	34	15	13
Units: months				
median (confidence interval 95%)	11.4 (8.1 to 15.1)	11.8 (5.5 to 9999)	8.6 (2.1 to 9999)	5.8 (4.6 to 9999)

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Pooled Sub-cohort	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	24	27	27	
Units: months				
median (confidence interval 95%)	10.5 (6.7 to 9999)	7.2 (5.6 to 9999)	999 (12.2 to 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS) ^[16]
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End point description:

An OS was defined as the time (in months) from the date of the first dose to the death date. In the absence of death confirmation or for subjects alive as of the OS cut-off date, survival time was censored at the date of last study follow-up, or the cut-off date, whichever was earlier. Efficacy population included all treated iCCA subjects with confirmed FGFR2 gene fusions or other FGFR2 rearrangements who had received at least 1 dose of TAS-120.

End point type	Secondary
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End point timeframe:

Up to approximately 37.5 months (through cut-off date 29-May-2021)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: months				
median (confidence interval 95%)	20.0 (16.4 to 24.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Mobility Scores at Specified Visits

End point title	Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Mobility Scores at Specified Visits ^[17]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was rated on 3 levels of function: no problem, some problem and extreme problem. In this outcome measure, data were reported categorically as the number of subjects who chose each category. Patient-reported outcomes (PRO) Population that included all subjects who had received TAS-120 treatment and had EQ-5D-3L assessment at Baseline and at least one subsequent post-baseline assessment. Here, 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in the Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: Count of subjects				
Baseline - No Problem (n=90)	72			
Baseline - Some Problem (n=90)	18			
Baseline - Extreme Problem (n=90)	0			
Cycle 2 - No Problem (n=81)	60			
Cycle 2 - Some Problem (n=81)	20			
Cycle 2 - Extreme Problem (n=81)	1			
Cycle 4 - No Problem (n=78)	60			
Cycle 4 - Some Problem (n=78)	18			
Cycle 4 - Extreme Problem (n=78)	0			
Cycle 7 - No Problem (n= 65)	51			
Cycle 7 - Some Problem (n= 65)	14			
Cycle 7 - Extreme Problem (n= 65)	0			
Cycle 10 - No Problem (n= 58)	42			
Cycle 10 - Some Problem (n= 58)	16			

Cycle 10 - Extreme Problem (n= 58)	0			
Cycle 13 - No Problem (n= 47)	32			
Cycle 13 - Some Problem (n= 47)	15			
Cycle 13 - Extreme Problem (n= 47)	0			
Cycle 16 - No Problem (n= 35)	23			
Cycle 16 - Some Problem (n= 35)	12			
Cycle 16 - Extreme Problem (n= 35)	0			
Cycle 19 - No Problem (n= 28)	16			
Cycle 19 - Some Problem (n= 28)	12			
Cycle 19 - Extreme Problem (n= 28)	0			
Cycle 22 - No Problem (n= 21)	9			
Cycle 22 - Some Problem (n= 21)	12			
Cycle 22 - Extreme Problem (n= 21)	0			
Cycle 25 - No Problem (n= 12)	9			
Cycle 25 - Some Problem (n= 12)	2			
Cycle 25 - Extreme Problem (n= 12)	1			
Cycle 28 - No Problem (n= 8)	6			
Cycle 28 - Some Problem (n= 8)	2			
Cycle 28 - Extreme Problem (n= 8)	0			
Cycle 31 - No Problem (n= 3)	3			
Cycle 31 - Some Problem (n= 3)	0			
Cycle 31 - Extreme Problem (n= 3)	0			
Cycle 34 - No Problem (n= 3)	3			
Cycle 34 - Some Problem (n= 3)	0			
Cycle 34 - Extreme Problem (n= 3)	0			
Cycle 37 - No Problem (n= 3)	2			
Cycle 37 - Some Problem (n= 3)	1			
Cycle 37 - Extreme Problem (n= 3)	0			
Cycle 40 - No Problem (n= 1)	0			
Cycle 40 - Some Problem (n= 1)	1			
Cycle 40 - Extreme Problem (n= 1)	0			
End of Treatment - No Problem (n= 44)	23			
End of Treatment - Some Problem (n= 44)	20			
End of Treatment - Extreme Problem (n= 44)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Self-care Scores at Specified Visits

End point title	Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Self-care Scores at Specified Visits ^[18]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was rated on 3 levels of function: no problem, some problem and extreme problem. In this outcome measure, data were reported categorically as the number of subjects who chose each category. Analysis was performed on PRO population. Here, 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months])

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: Count of subjects				
Baseline - No Problem (n=90)	82			
Baseline - Some Problem (n=90)	8			
Baseline - Extreme Problem (n=90)	0			
Cycle 2 - No Problem (n=81)	75			
Cycle 2 - Some Problem (n=81)	6			
Cycle 2 - Extreme Problem (n=81)	0			
Cycle 4 - No Problem (n=78)	70			
Cycle 4 - Some Problem (n=78)	7			
Cycle 4 - Extreme Problem (n=78)	1			
Cycle 7 - No Problem (n=65)	58			
Cycle 7 - Some Problem (n=65)	6			
Cycle 7 - Extreme Problem (n=65)	1			
Cycle 10 - No Problem (n=58)	52			
Cycle 10 - Some Problem (n=58)	6			
Cycle 10 - Extreme Problem (n=58)	1			
Cycle 13 - No Problem (n=47)	41			
Cycle 13 - Some Problem (n=47)	6			
Cycle 13 - Extreme Problem (n=47)	0			
Cycle 16 - No Problem (n=35)	30			
Cycle 16 - Some Problem (n=35)	4			
Cycle 16 - Extreme Problem (n=35)	1			
Cycle 19 - No Problem (n=28)	22			
Cycle 19 - Some Problem (n=28)	6			
Cycle 19 - Extreme Problem (n=28)	0			
Cycle 22 - No Problem (n=21)	18			
Cycle 22 - Some Problem (n=21)	3			
Cycle 22 - Extreme Problem (n=21)	0			
Cycle 25 - No Problem (n=12)	9			
Cycle 25 - Some Problem (n=12)	3			
Cycle 25 - Extreme Problem (n=12)	0			
Cycle 28 - No Problem (n=8)	8			
Cycle 28 - Some Problem (n=8)	0			
Cycle 28 - Extreme Problem (n=8)	0			
Cycle 31 - No Problem (n=3)	3			
Cycle 31 - Some Problem (n=3)	0			
Cycle 31 - Extreme Problem (n=3)	0			
Cycle 34 - No Problem (n=3)	3			
Cycle 34 - Some Problem (n=3)	0			

Cycle 34 - Extreme Problem (n=3)	0			
Cycle 37 - No Problem (n=3)	2			
Cycle 37 - Some Problem (n=3)	1			
Cycle 37 - Extreme Problem (n=3)	0			
Cycle 40 - No Problem (n=1)	1			
Cycle 40 - Some Problem (n=1)	0			
Cycle 40 - Extreme Problem (n=1)	0			
End of Treatment - No Problem (n= 43)	34			
End of Treatment - Some Problem (n= 43)	8			
End of Treatment - Extreme Problem (n= 43)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Usual Activities Scores at Specified Visits

End point title	Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Usual Activities Scores at Specified Visits ^[19]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was rated on 3 levels of function: no problem, some problem and extreme problem. In this outcome measure, data were reported categorically as the number of subjects who chose each category. Analysis was performed on PRO population. Here 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: Count of subjects				
Baseline - No Problem (n= 89)	63			
Baseline - Some Problem (n= 89)	24			
Baseline - Extreme Problem (n= 89)	2			
Cycle 2 - No Problem (n= 81)	47			
Cycle 2 - Some Problem (n= 81)	32			
Cycle 2 - Extreme Problem (n= 81)	2			
Cycle 4 - No Problem (n= 78)	50			
Cycle 4 - Some Problem (n= 78)	27			
Cycle 4 - Extreme Problem (n= 78)	1			

Cycle 7 - No Problem (n= 65)	43			
Cycle 7 - Some Problem (n= 65)	20			
Cycle 7 - Extreme Problem (n= 65)	2			
Cycle 10 - No Problem (n= 58)	34			
Cycle 10 - Some Problem (n= 58)	23			
Cycle 10 - Extreme Problem (n= 58)	1			
Cycle 13 - No Problem (n= 47)	28			
Cycle 13 - Some Problem (n= 47)	19			
Cycle 13 - Extreme Problem (n= 47)	0			
Cycle 16 - No Problem (n= 35)	20			
Cycle 16 - Some Problem (n= 35)	14			
Cycle 16 - Extreme Problem (n= 35)	1			
Cycle 19 - No Problem (n= 28)	15			
Cycle 19 - Some Problem (n= 28)	12			
Cycle 19 - Extreme Problem (n= 28)	1			
Cycle 22 - No Problem (n= 21)	7			
Cycle 22 - Some Problem (n= 21)	14			
Cycle 22 - Extreme Problem (n= 21)	0			
Cycle 25 - No Problem (n= 12)	4			
Cycle 25 - Some Problem (n= 12)	7			
Cycle 25 - Extreme Problem (n= 12)	1			
Cycle 28 - No Problem (n= 8)	3			
Cycle 28 - Some Problem (n= 8)	5			
Cycle 28 - Extreme Problem (n= 8)	0			
Cycle 31 - No Problem (n= 3)	1			
Cycle 31 - Some Problem (n= 3)	2			
Cycle 31 - Extreme Problem (n= 3)	0			
Cycle 34 - No Problem (n= 3)	2			
Cycle 34 - Some Problem (n= 3)	1			
Cycle 34 - Extreme Problem (n= 3)	0			
Cycle 37 - No Problem (n= 3)	0			
Cycle 37 - Some Problem (n= 3)	3			
Cycle 37 - Extreme Problem (n= 3)	0			
Cycle 40 - No Problem (n= 1)	0			
Cycle 40 - Some Problem (n= 1)	1			
Cycle 40 - Extreme Problem (n= 1)	0			
End of Treatment - No Problem (n= 44)	16			
End of Treatment - Some Problem (n= 44)	25			
End of Treatment - Extreme Problem (n= 44)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Pain/Discomfort Scores at Specified Visits

End point title	Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Pain/Discomfort Scores at Specified Visits ^[20]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was rated on 3 levels of function: no problem, some problem and extreme problem. In this outcome measure, data were reported categorically as the number of subjects who chose each category. Analysis was performed on PRO population. Here, 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: Count of subjects				
Baseline - No Problem (n=90)	42			
Baseline - Some Problem (n=90)	47			
Baseline - Extreme Problem (n=90)	1			
Cycle 2 - No Problem (n=81)	45			
Cycle 2 - Some Problem (n=81)	35			
Cycle 2 - Extreme Problem (n=81)	1			
Cycle 4 - No Problem (n=78)	40			
Cycle 4 - Some Problem (n=78)	36			
Cycle 4 - Extreme Problem (n=78)	2			
Cycle 7 - No Problem (n=66)	36			
Cycle 7 - Some Problem (n=66)	29			
Cycle 7 - Extreme Problem (n=66)	1			
Cycle 10 - No Problem (n=58)	30			
Cycle 10 - Some Problem (n=58)	26			
Cycle 10 - Extreme Problem (n=58)	2			
Cycle 13 - No Problem (n=47)	23			
Cycle 13 - Some Problem (n=47)	22			
Cycle 13 - Extreme Problem (n=47)	2			
Cycle 16 - No Problem (n=35)	13			
Cycle 16 - Some Problem (n=35)	19			
Cycle 16 - Extreme Problem (n=35)	3			
Cycle 19 - No Problem (n=28)	13			
Cycle 19 - Some Problem (n=28)	15			
Cycle 19 - Extreme Problem (n=28)	0			
Cycle 22 - No Problem (n=21)	6			
Cycle 22 - Some Problem (n=21)	14			
Cycle 22 - Extreme Problem (n=21)	1			
Cycle 25 - No Problem (n=12)	3			
Cycle 25 - Some Problem (n=12)	9			
Cycle 25 - Extreme Problem (n=12)	0			
Cycle 28 - No Problem (n=8)	2			
Cycle 28 - Some Problem (n=8)	5			

Cycle 28 - Extreme Problem (n=8)	1			
Cycle 31 - No Problem (n=3)	2			
Cycle 31 - Some Problem (n=3)	1			
Cycle 31 - Extreme Problem (n=3)	0			
Cycle 34 - No Problem (n=3)	3			
Cycle 34 - Some Problem (n=3)	0			
Cycle 34 - Extreme Problem (n=3)	0			
Cycle 37 - No Problem (n=3)	2			
Cycle 37 - Some Problem (n=3)	1			
Cycle 37 - Extreme Problem (n=3)	0			
Cycle 40 - No Problem (n=1)	0			
Cycle 40 - Some Problem (n=1)	1			
Cycle 40 - Extreme Problem (n=1)	0			
End of Treatment - No Problem (n=44)	12			
End of Treatment - Some Problem (n=44)	27			
End of Treatment - Extreme Problem (n=44)	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Anxiety/Depression Scores at Specified Visits

End point title	Phase 2: European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) Questionnaire: Anxiety/Depression Scores at Specified Visits ^[21]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension was rated on 3 levels of function: no problem, some problem and extreme problem. In this outcome measure, data were reported categorically as the number of subjects who chose each category. Analysis was performed on PRO population. Here, 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: Count of subjects				
Baseline - No Problem (n= 89)	64			
Baseline - Some Problem (n= 89)	25			
Baseline - Extreme Problem (n= 89)	0			

Cycle 2 - No Problem (n= 81)	66			
Cycle 2 - Some Problem (n= 81)	15			
Cycle 2 - Extreme Problem (n= 81)	0			
Cycle 4 - No Problem (n= 78)	63			
Cycle 4 - Some Problem (n= 78)	15			
Cycle 4 - Extreme Problem (n= 78)	0			
Cycle 7 - No Problem (n= 65)	48			
Cycle 7 - Some Problem (n= 65)	15			
Cycle 7 - Extreme Problem (n= 65)	2			
Cycle 10 - No Problem (n= 58)	44			
Cycle 10 - Some Problem (n= 58)	12			
Cycle 10 - Extreme Problem (n= 58)	2			
Cycle 13 - No Problem (n= 47)	36			
Cycle 13 - Some Problem (n= 47)	11			
Cycle 13 - Extreme Problem (n= 47)	0			
Cycle 16 - No Problem (n= 35)	26			
Cycle 16 - Some Problem (n= 35)	8			
Cycle 16 - Extreme Problem (n= 35)	1			
Cycle 19 - No Problem (n= 23)	21			
Cycle 19 - Some Problem (n= 23)	6			
Cycle 19 - Extreme Problem (n= 23)	1			
Cycle 22 - No Problem (n= 21)	13			
Cycle 22 - Some Problem (n= 21)	8			
Cycle 22 - Extreme Problem (n= 21)	0			
Cycle 25 - No Problem (n= 12)	8			
Cycle 25 - Some Problem (n= 12)	4			
Cycle 25 - Extreme Problem (n= 12)	0			
Cycle 28 - No Problem (n= 8)	5			
Cycle 28 - Some Problem (n= 8)	3			
Cycle 28 - Extreme Problem (n= 8)	0			
Cycle 31 - No Problem (n= 3)	2			
Cycle 31 - Some Problem (n= 3)	1			
Cycle 31 - Extreme Problem (n= 3)	0			
Cycle 34 - No Problem (n= 3)	2			
Cycle 34 - Some Problem (n= 3)	1			
Cycle 34 - Extreme Problem (n= 3)	0			
Cycle 37 - No Problem (n= 3)	1			
Cycle 37 - Some Problem (n= 3)	2			
Cycle 37 - Extreme Problem (n= 3)	0			
Cycle 40 - No Problem (n= 1)	0			
Cycle 40 - Some Problem (n= 1)	1			
Cycle 40 - Extreme Problem (n= 1)	0			
End of Treatment - No Problem (n= 44)	22			
End of Treatment - Some Problem (n= 44)	19			
End of Treatment - Extreme Problem (n= 44)	3			

Statistical analyses

Secondary: Phase 2: Change From Baseline in EQ-5D-3L Visual Analogue Scale (VAS) at Specified Visits

End point title	Phase 2: Change From Baseline in EQ-5D-3L Visual Analogue Scale (VAS) at Specified Visits ^[22]
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End point description:

EQ-5D-3L was a self-administered standardized questionnaire to assess health outcome. It comprised 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. A vertical VAS allows the subjects to indicate their health state that day, and ranged from 0 (worst imaginable) to 100 (best imaginable), with higher scores indicating better health state. Analysis was performed on PRO population. Here, 'n' = number of subjects with available data for each specified category. '9999' signifies that the SD was not calculable for 1 subject.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 88)	71.72 (± 20.307)			
Change at Cycle 2 (n= 77)	-0.73 (± 19.409)			
Change at Cycle 4 (n= 74)	-1.04 (± 23.984)			
Change at Cycle 7 (n= 62)	-1.82 (± 29.984)			
Change at Cycle 10 (n= 54)	0.40 (± 30.428)			
Change at Cycle 13 (n= 45)	4.76 (± 26.585)			
Change at Cycle 16 (n= 33)	-1.71 (± 34.417)			
Change at Cycle 19 (n= 27)	1.76 (± 25.155)			
Change at Cycle 22 (n= 20)	1.85 (± 31.707)			
Change at Cycle 25 (n= 11)	-0.82 (± 45.828)			
Change at Cycle 28 (n= 8)	-1.85 (± 40.912)			
Change at Cycle 31 (n= 3)	18.17 (± 17.280)			
Change at Cycle 34 (n= 3)	19.00 (± 19.313)			
Change at Cycle 37 (n= 3)	15.17 (± 21.624)			
Change at Cycle 40 (n= 1)	15.00 (± 9999)			

End of Treatment (n= 44)	-8.89 (± 26.272)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) Global Health Status Score at Specified Timepoints

End point title	Phase 2: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) Global Health Status Score at Specified Timepoints ^[23]
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End point description:

The EORTC QLQ-C30 is a 30-item cancer-specific tool used to evaluate chemotherapy effects and subject-reported outcomes. It covers global health status/quality of life (GHS/QOL), five functional scales (physical, role, cognitive, emotional, social), three symptom scales (fatigue, pain, nausea/vomiting), and six single items (dyspnea, appetite loss, insomnia, constipation, diarrhea, financial difficulties). Most items use a 4-point scale (1=Not at All to 4=Very Much), while Items 29–30 form the GHS scale, scored on a 7-point scale (1=Very Poor to 7=Excellent). GHS total score = $[(\{Q29+Q30\}/2)-1]/6 \times 100$. Scores range from 0 (worst) to 100 (best); higher scores indicate better quality of life. '9999' signifies that upper limit of 95% confidence interval (CI) was not estimable due to the smaller number of subjects with events. Analysis was performed on PRO population. Here, 'n' = number of subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40 and end of treatment (i.e., Cycle 43 [30 months]).

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline (n= 91)	70.1 (± 19.41)			
Change at Cycle 2 (n= 83)	-1.0 (± 22.02)			
Change at Cycle 4 (n=79)	0.4 (± 20.62)			
Change at Cycle 7 (n= 65)	-0.5 (± 21.64)			
Change at Cycle 10 (n= 58)	1.9 (± 22.84)			
Change at Cycle 13 (n= 48)	0.9 (± 21.49)			
Change at Cycle 16 (n= 27)	2.5 (± 18.61)			
Change at Cycle 19 (n= 15)	-1.7 (± 17.31)			
Change at Cycle 22 (n= 11)	-8.3 (± 22.05)			
Change at Cycle 25 (n= 7)	-4.8 (± 21.44)			
Change at Cycle 28 (n= 4)	-6.3 (± 12.50)			
Change at Cycle 31 (n= 1)	41.7 (± 9999)			

Change at Cycle 34 (n= 1)	41.7 (± 9999)			
End of Treatment (n=30)	-7.5 (± 23.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Dose Expansion: Number of Subjects with Any Adverse Events (AEs) and Any Serious AEs (SAEs)

End point title	Phase 1: Dose Expansion: Number of Subjects with Any Adverse Events (AEs) and Any Serious AEs (SAEs) ^[24]
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End point description:

An AE was defined as any untoward medical condition that occurred in a subject from the time the ICF was signed and does not necessarily had a causal relationship with the use of the product. An SAE was an AE that falls into one or more of the following categories: a. resulted in death, b. was life threatening, c. required inpatient hospitalization or prolongation of existing hospitalization, d. resulted in persistent or significant disability or incapacity, e. was a congenital anomaly/birth defect, f. other important medical event. Safety Population subjects included all subjects who had received at least 1 dose of TAS-120.

End point type	Secondary
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End point timeframe:

From the first dose up to approximately 50.5 months (through cut-off date 29-May-2021).

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 1 as pre-specified in Protocol and SAP.

End point values	Phase 1: Dose Expansion Cohort 1	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	34	15	13
Units: Count of subjects				
AEs	57	34	15	13
SAEs	27	13	10	9

End point values	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Sub-cohort 1	Phase 1: Dose Expansion: Sub-cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	27	19	8
Units: Count of subjects				
AEs	23	26	18	5
SAEs	13	14	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Subjects with Any Adverse Events (AEs) and Any Serious Adverse Events (SAEs)

End point title	Phase 2: Number of Subjects with Any Adverse Events (AEs) and Any Serious Adverse Events (SAEs) ^[25]
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End point description:

An AE was defined as any untoward medical condition that occurs in a subject from the time the ICF was signed and does not necessarily had a causal relationship with the use of the product. An SAE was an AE that falls into one or more of the following categories: a. resulted in death, b. was life threatening, c. required inpatient hospitalization or prolongation of existing hospitalization, d. resulted in persistent or significant disability or incapacity, e. was a congenital anomaly/birth defect, f. other important medical event. Safety Population included all subjects who had received at least 1 dose of TAS-120.

End point type	Secondary
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End point timeframe:

From the first dose up to approximately 37.5 months (through cut-off date 29-May-2021).

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure was planned to be reported for only Cohort 2 as pre-specified in Protocol and SAP.

End point values	Phase 2			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: Count of subjects				
AEs	103			
SAEs	42			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose administration up to approximately up to 59.5 months for Phase 1 Dose escalation; up to 50.5 months for Phase 1 Dose expansion Cohorts and up to 37.5 months for Phase 2

Adverse event reporting additional description:

Safety Population included all subjects who had received at least 1 dose of TAS-120. MedDRA version 17.0 for Phase 1 and MedDRA version 22.0 for Phase 2. Safety analysis were done based on data cut-off dates: 12 July 2019 for Phase 1 Dose Escalation, 29-May-2021 for Phase 1 Dose Expansion and Phase 2.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0, 22.0

Reporting groups

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 8 mg
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Reporting group description:

Subjects with or without fibroblast growth factor [FGF]/fibroblast growth factor receptor [FGFR] gene abnormalities received TAS-120 8 milligrams (mg) orally every other day (QOD; Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 16 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 16 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 24 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 24 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 36 mg
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Reporting group description:

Subjects with or without FGF/FGFR gene abnormalities received TAS-120 36 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 56 mg
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Reporting group description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 56 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 80 mg
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Reporting group description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 80 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 120 mg
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Reporting group description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 120 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 160 mg
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Reporting group description:

Subjects with FGF/FGFR gene abnormalities received TAS-120 160 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.

Reporting group title	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Reporting group description: Subjects with FGF/FGFR gene abnormalities received TAS-120 200 mg orally QOD (Monday, Wednesday and Friday of each week) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 4 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 4 mg orally once daily (QD) in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 8 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 8 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 16 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 16 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 20 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 20 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Escalation: QD Dosing: 24 mg
Reporting group description: Subjects with or without FGF/FGFR gene abnormalities received a dose between 24 mg orally QD in a 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death.	
Reporting group title	Phase 1: Dose Expansion Cohort 1
Reporting group description: Subjects with intra-hepatic or extrahepatic cholangiocarcinoma (iCCA or eCCA) harboring FGFR2 gene fusions or rearrangements and who were treated or not treated with prior FGFR inhibitors received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 33.5 months).	
Reporting group title	Phase 1: Dose Expansion: Cohort 2
Reporting group description: Subjects with primary central nervous system (CNS) tumors harboring FGFR gene fusions or FGFR1 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 28.5 months).	
Reporting group title	Phase 1: Dose Expansion: Cohort 3
Reporting group description: Subjects with advanced urothelial carcinoma harboring FGFR3 gene fusions or FGFR3 activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 9.6 months).	
Reporting group title	Phase 1: Dose Expansion: Cohort 4
Reporting group description: Subjects with breast or gastric cancer with harboring FGFR2 amplification received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 5.5 months).	
Reporting group title	Phase 1: Dose Expansion: Cohort 5
Reporting group description: Subjects with tumor types harboring FGFR gene fusions or activating mutations received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 42.5 months).	
Reporting group title	Phase 1: Dose Expansion: Cohort 6
Reporting group description: Subjects who were not included in Cohorts 1 to 5 received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 11 months).	

Reporting group title	Phase 1: Dose Expansion: Sub-cohort 2
Reporting group description: Subjects with other tumor types who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 45.5 months).	
Reporting group title	Phase 1: Dose Expansion: Sub-cohort 1
Reporting group description: Subjects with iCCA who were enrolled prior to the confirmation of the RP2D received TAS-120 16 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum exposure: 28 months).	
Reporting group title	Phase 2
Reporting group description: Subjects with iCCA with tumors harboring FGFR2 gene rearrangements received TAS-120 20 mg tablets orally QD in each of 21-day treatment cycle until disease progression, unacceptable toxicity, withdrawal of consent or death (maximum duration: 30 months).	

Serious adverse events	Phase 1: Dose Escalation: QOD Dosing: 8 mg	Phase 1: Dose Escalation: QOD Dosing: 16 mg	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous			

system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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				
Asthenia				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Death				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Disease progression				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Fatigue				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Gait disturbance				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
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 physical health deterioration				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Non-cardiac chest pain				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
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				
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Suprapubic pain				

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 thrombosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 distress			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 fibrillation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	Phase 1: Dose Escalation: QOD Dosing: 36 mg	Phase 1: Dose Escalation: QOD Dosing: 56 mg	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 5 (40.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Metastases to central nervous system			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oncologic complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 associated fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	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
Suprapubic pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Troponin T increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Muscle strain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Post procedural fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Wound haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 fibrillation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Extrapyramidal disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Focal dyscognitive seizures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Intracranial mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neurological symptom			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Papilloedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Retinal detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Duodenal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematochezia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Melaena			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Obstruction gastric			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oesophageal ulcer			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oesophagitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Small intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bile duct stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cholangitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hepatic failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haemarthrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Appendicitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Biliary sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Biliary tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Corona virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Lung infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Peritonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Peritonitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Splenic abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypercalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Serious adverse events	Phase 1: Dose Escalation: QOD Dosing: 120 mg	Phase 1: Dose Escalation: QOD Dosing: 160 mg	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	7 / 8 (87.50%)	4 / 7 (57.14%)
number of deaths (all causes)	1	0	2
number of deaths resulting from adverse events	1	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 4 (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 ascites			
subjects affected / exposed	0 / 4 (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 neoplasm progression			
subjects affected / exposed	0 / 4 (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 pleural effusion			
subjects affected / exposed	0 / 4 (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
Metastases to central nervous system			

subjects affected / exposed	0 / 4 (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
Oncologic complication			
subjects affected / exposed	0 / 4 (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
Tumour associated fever			
subjects affected / exposed	0 / 4 (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
Tumour pain			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Hypotension			
subjects affected / exposed	0 / 4 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (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			

Asthenia			
subjects affected / exposed	0 / 4 (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
Death			
subjects affected / exposed	0 / 4 (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
Disease progression			
subjects affected / exposed	0 / 4 (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 / 1
Fatigue			
subjects affected / exposed	0 / 4 (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
Gait disturbance			
subjects affected / exposed	0 / 4 (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 physical health deterioration			
subjects affected / exposed	0 / 4 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Suprapubic pain			

subjects affected / exposed	0 / 4 (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
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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 thrombosis			

subjects affected / exposed	0 / 4 (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
Respiratory distress			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Respiratory failure			
subjects affected / exposed	0 / 4 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (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
Disorientation			
subjects affected / exposed	0 / 4 (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
Mental status changes			
subjects affected / exposed	0 / 4 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (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 bilirubin increased			
subjects affected / exposed	0 / 4 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (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
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 4 (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
Troponin T increased			
subjects affected / exposed	0 / 4 (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			
Fall			
subjects affected / exposed	0 / 4 (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
Femur fracture			
subjects affected / exposed	0 / 4 (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
Humerus fracture			
subjects affected / exposed	0 / 4 (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
Muscle strain			

subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Post procedural fever			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Spinal compression fracture			
subjects affected / exposed	0 / 4 (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
Subdural haematoma			
subjects affected / exposed	0 / 4 (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
Wound haemorrhage			
subjects affected / exposed	0 / 4 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (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
Atrial fibrillation			

subjects affected / exposed	0 / 4 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 4 (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
Aphasia			
subjects affected / exposed	0 / 4 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (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
Cognitive disorder			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Dysarthria			
subjects affected / exposed	0 / 4 (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
Extrapyramidal disorder			

subjects affected / exposed	0 / 4 (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
Focal dyscognitive seizures			
subjects affected / exposed	0 / 4 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 4 (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
Headache			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Intracranial mass			
subjects affected / exposed	0 / 4 (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
Migraine			
subjects affected / exposed	0 / 4 (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 disorder			
subjects affected / exposed	0 / 4 (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
Neurological symptom			

subjects affected / exposed	0 / 4 (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
Paraesthesia			
subjects affected / exposed	0 / 4 (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
Presyncope			
subjects affected / exposed	0 / 4 (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
Seizure			
subjects affected / exposed	0 / 4 (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
Spinal cord compression			
subjects affected / exposed	0 / 4 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 4 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 4 (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			

subjects affected / exposed	0 / 4 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (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
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 4 (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
Papilloedema			
subjects affected / exposed	0 / 4 (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
Retinal detachment			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (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
Ascites			
subjects affected / exposed	0 / 4 (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
Colitis			

subjects affected / exposed	0 / 4 (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
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Duodenal obstruction			
subjects affected / exposed	0 / 4 (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
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haematochezia			

subjects affected / exposed	0 / 4 (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
Ileus			
subjects affected / exposed	0 / 4 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 4 (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
Inguinal hernia			
subjects affected / exposed	0 / 4 (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
Intestinal obstruction			
subjects affected / exposed	0 / 4 (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
Melaena			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Obstruction gastric			
subjects affected / exposed	0 / 4 (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
Oesophageal ulcer			

subjects affected / exposed	0 / 4 (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
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 4 (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
Oesophagitis			
subjects affected / exposed	0 / 4 (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
Oesophagitis ulcerative			
subjects affected / exposed	0 / 4 (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
Pancreatitis acute			
subjects affected / exposed	0 / 4 (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
Small intestinal haemorrhage			
subjects affected / exposed	0 / 4 (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
Stomatitis			
subjects affected / exposed	0 / 4 (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
Umbilical hernia			
subjects affected / exposed	0 / 4 (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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 4 (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
Bile duct stenosis			
subjects affected / exposed	0 / 4 (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
Cholangitis			
subjects affected / exposed	0 / 4 (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
Cholangitis acute			
subjects affected / exposed	0 / 4 (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
Cholecystitis			
subjects affected / exposed	0 / 4 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 4 (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
Hepatic failure			

subjects affected / exposed	0 / 4 (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
Jaundice			
subjects affected / exposed	0 / 4 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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 incontinence			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Haemarthrosis			
subjects affected / exposed	0 / 4 (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
Muscular weakness			
subjects affected / exposed	0 / 4 (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
Myalgia			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
Appendicitis			
subjects affected / exposed	0 / 4 (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
Biliary sepsis			
subjects affected / exposed	0 / 4 (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
Biliary tract infection			

subjects affected / exposed	0 / 4 (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
Bronchitis			
subjects affected / exposed	0 / 4 (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
Cellulitis			
subjects affected / exposed	0 / 4 (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
Corona virus infection			
subjects affected / exposed	0 / 4 (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
Cystitis			
subjects affected / exposed	0 / 4 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Lung infection			

subjects affected / exposed	0 / 4 (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
Paronychia			
subjects affected / exposed	0 / 4 (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
Peritonitis			
subjects affected / exposed	0 / 4 (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
Peritonitis bacterial			
subjects affected / exposed	0 / 4 (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
Pharyngitis			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Sepsis			
subjects affected / exposed	0 / 4 (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
Splenic abscess			
subjects affected / exposed	0 / 4 (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			

subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Wound infection			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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
Failure to thrive			
subjects affected / exposed	0 / 4 (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
Hypercalcaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (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
Hyperkalaemia			
subjects affected / exposed	0 / 4 (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
Hypoglycaemia			

subjects affected / exposed	0 / 4 (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			
subjects affected / exposed	0 / 4 (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	Phase 1: Dose Escalation: QD Dosing: 4 mg	Phase 1: Dose Escalation: QD Dosing: 8 mg	Phase 1: Dose Escalation: QD Dosing: 16 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	9 / 14 (64.29%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			

Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suprapubic pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 thrombosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 distress			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 fibrillation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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 incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
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	Phase 1: Dose Escalation: QD Dosing: 20 mg	Phase 1: Dose Escalation: QD Dosing: 24 mg	Phase 1: Dose Expansion Cohort 1
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	6 / 14 (42.86%)	27 / 57 (47.37%)
number of deaths (all causes)	1	1	40
number of deaths resulting from adverse events	1	1	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 neoplasm progression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			

Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Disease progression			
subjects affected / exposed	2 / 7 (28.57%)	1 / 14 (7.14%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suprapubic pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 thrombosis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 distress			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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
Disorientation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 fibrillation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	0 / 57 (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
Duodenal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Jaundice			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
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 incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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

Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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
Corona virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (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
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	0 / 57 (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
Sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
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	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 34 (38.24%)	10 / 15 (66.67%)	9 / 13 (69.23%)
number of deaths (all causes)	22	12	11
number of deaths resulting from adverse events	0	3	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 ascites			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 neoplasm progression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant pleural effusion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Oncologic complication			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	0 / 13 (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
Hypertension			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			

Asthenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 34 (0.00%)	3 / 15 (20.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Fatigue			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
General physical health deterioration			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	0 / 13 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suprapubic pain			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
Aspiration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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 thrombosis			

subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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 distress			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Mental status changes			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Troponin T increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 fibrillation			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Migraine			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Presyncope			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Spinal cord compression			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Duodenal obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematemesis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
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 incontinence			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Myalgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Pneumonia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (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
Sepsis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			

subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Urosepsis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (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
Wound infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
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	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Sub-cohort 2
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 24 (54.17%)	14 / 27 (51.85%)	0 / 8 (0.00%)
number of deaths (all causes)	15	17	1
number of deaths resulting from adverse events	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 ascites			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 neoplasm progression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 pleural effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Metastases to central nervous system			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Oncologic complication			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 associated fever			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Death			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Disease progression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fatigue			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (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
Gait disturbance			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 physical health deterioration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Suprapubic pain			

subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Dyspnoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Pneumonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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 thrombosis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 distress			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 failure			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Disorientation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Mental status changes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 bilirubin increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Troponin T increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Femur fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Humerus fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Muscle strain			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Post procedural fever			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Spinal compression fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Subdural haematoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Wound haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Atrial fibrillation			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Aphasia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Cognitive disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Dizziness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Dysarthria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Extrapyramidal disorder			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Focal dyscognitive seizures			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Intracranial mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Migraine			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Neurological symptom			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Presyncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Seizure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Spinal cord compression			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			

subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Eye disorders			
Cataract			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Papilloedema			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Retinal detachment			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (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
Abdominal pain upper			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (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
Ascites			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Colitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Duodenal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Dysphagia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Gastric haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Haematemesis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Haematochezia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Ileus			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Inguinal hernia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Intestinal obstruction			
subjects affected / exposed	2 / 24 (8.33%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Obstruction gastric			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Oesophageal ulcer			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Oesophagitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Oesophagitis ulcerative			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Pancreatitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Small intestinal haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (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
Umbilical hernia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 gastrointestinal haemorrhage			

subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Bile duct stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Cholangitis			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Cholecystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hepatic failure			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Jaundice			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 incontinence			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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 retention			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Haemarthrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Muscular weakness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Myalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
Appendicitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Biliary sepsis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Biliary tract infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Bronchitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (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
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Corona virus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Cystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Lung infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Paronychia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Peritonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Peritonitis bacterial			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	3 / 27 (11.11%)	0 / 8 (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
Splenic abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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 infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Urosepsis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Wound infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (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
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (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
Failure to thrive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hypercalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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
Hypoglycaemia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (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

Serious adverse events	Phase 1: Dose Expansion: Sub-cohort 1	Phase 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (0.00%)	42 / 103 (40.78%)	
number of deaths (all causes)	9	58	
number of deaths resulting from adverse events	0	6	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant ascites			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant pleural effusion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oncologic complication			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tumour associated fever			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 19 (0.00%)	5 / 103 (4.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 4	
Fatigue			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suprapubic pain			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary thrombosis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood bilirubin increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrapyramidal disorder			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial mass			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological symptom			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloedema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colitis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophagitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Back pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona virus infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic abscess			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dehydration			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Failure to thrive			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			

subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Phase 1: Dose Escalation: QOD Dosing: 8 mg	Phase 1: Dose Escalation: QOD Dosing: 16 mg	Phase 1: Dose Escalation: QOD Dosing: 24 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device failure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Disease progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vulvovaginal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	0
Breast ulceration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ovarian vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Onychophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood phosphorus increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric pH decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Post procedural oedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stoma site pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Wound decomposition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nervous system disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lacrimation decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Optic nerve cupping			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Subretinal fluid			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Oesophageal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Anal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	3 / 3 (100.00%)	1 / 3 (33.33%)
occurrences (all)	0	3	3
Dry mouth			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	3	1
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bile duct stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertrichosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Itching scar			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nail disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Onychalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmoplantar keratoderma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Skin hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nail dystrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pain of skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin exfoliation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder prolapse			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proteinuria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Cellulitis staphylococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lung infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	2
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Calciphylaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	3
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Escalation: QOD Dosing: 36 mg	Phase 1: Dose Escalation: QOD Dosing: 56 mg	Phase 1: Dose Escalation: QOD Dosing: 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Breast ulceration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Ovarian vein thrombosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0
Dyspnoea exertional			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry throat			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypoventilation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Onychophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Weight increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Platelet count increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastric pH decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound decomposition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Seizure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Tinnitus			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Vertigo			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Cerumen impaction			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Eye disorders			
Cataract			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Cataract nuclear			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Cataract subcapsular			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Chorioretinopathy			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Dry eye			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1
Eye irritation			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Eye pain			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Growth of eyelashes			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0

Keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Optic nerve cupping			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vitreous adhesions			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Retinal detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Oesophageal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingival oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abdominal distension			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Intestinal obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bile duct stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Itching scar			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Palmoplantar keratoderma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2

Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin fissures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nail bed tenderness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Onychoclasia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urticaria contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bladder prolapse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypopituitarism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Lung infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Paronychia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Pharyngitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Urosepsis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0

Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1
Folliculitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Localised infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Onychomycosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1
Sepsis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 1
Oral fungal infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Bronchitis viral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Oesophageal candidiasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Pelvic abscess subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0

Stoma site infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Metabolism and nutrition disorders			
Calciphylaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hyperphosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	4 / 5 (80.00%) 7
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Hypokalaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	3
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	8
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Escalation: QOD Dosing: 120 mg	Phase 1: Dose Escalation: QOD Dosing: 160 mg	Phase 1: Dose Escalation: QOD Dosing: 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	8 / 8 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	2	6	1
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Xerosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Device failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ovarian vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Libido decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Bilirubin conjugated increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	0 / 7 (0.00%)
occurrences (all)	0	6	0
Blood phosphorus increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastric pH decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound decomposition			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Wound haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Headache			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	1 / 7 (14.29%)
occurrences (all)	0	6	1
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2

Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Seizure subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Taste disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Cognitive disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Aphasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1
Ataxia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Dysarthria subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Encephalopathy subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Migraine with aura subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Partial seizures subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 2

Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 4 (50.00%)	4 / 8 (50.00%)	1 / 7 (14.29%)
occurrences (all)	3	8	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy mediastinal			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Growth of eyelashes			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Keratitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lacrimation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Optic nerve cupping			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pinguecula			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Subretinal fluid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Vitreous detachment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 8 (37.50%)	3 / 7 (42.86%)
occurrences (all)	4	4	4
Oesophageal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	2	7	1
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	3 / 8 (37.50%)	2 / 7 (28.57%)
occurrences (all)	2	4	2
Cheilitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 4 (50.00%)	4 / 8 (50.00%)	1 / 7 (14.29%)
occurrences (all)	2	10	1
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	6 / 8 (75.00%)	3 / 7 (42.86%)
occurrences (all)	5	7	6
Dry mouth			
subjects affected / exposed	3 / 4 (75.00%)	3 / 8 (37.50%)	2 / 7 (28.57%)
occurrences (all)	3	3	3
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Lip swelling subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Mouth ulceration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Intestinal obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Hepatobiliary disorders Cholecystitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Bile duct stenosis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Bile duct obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Itching scar			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nail discolouration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Nail disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	3	2
Onychomadesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Palmoplantar keratoderma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Onychoclasia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder prolapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Tendonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Osteolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 4 (50.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0

Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pelvic abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Calciphylaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	3 / 8 (37.50%)	2 / 7 (28.57%)
occurrences (all)	1	3	4
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	6	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Hyperphosphataemia			
subjects affected / exposed	3 / 4 (75.00%)	6 / 8 (75.00%)	6 / 7 (85.71%)
occurrences (all)	6	16	10
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	4	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Escalation: QD Dosing: 4 mg	Phase 1: Dose Escalation: QD Dosing: 8 mg	Phase 1: Dose Escalation: QD Dosing: 16 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 5 (100.00%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Infected neoplasm subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Vascular disorders Hot flush subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0	4 / 14 (28.57%) 4
Chills subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 3	2 / 14 (14.29%) 2
Influenza like illness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Xerosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Device failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Malaise			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	0 / 14 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Chest pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Breast ulceration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Ovarian vein thrombosis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0	2 / 14 (14.29%) 2
Dysphonia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Throat irritation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pleurisy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Rhinalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Onychophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Libido decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	2
Bilirubin conjugated increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Blood bilirubin increased			

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Blood calcium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood phosphorus increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastric pH decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Muscle rupture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wound decomposition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Lymph node pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Lymphadenopathy mediastinal subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Ear and labyrinth disorders			
Hypoacusis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	0 / 14 (0.00%) 0
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Cataract nuclear subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Cataract subcapsular subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Chorioretinopathy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	2 / 14 (14.29%) 2
Eye irritation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Optic nerve cupping			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vitreous adhesions			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Retinal detachment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Vitreous detachment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	4 / 14 (28.57%)
occurrences (all)	1	1	6
Oesophageal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	5 / 14 (35.71%)
occurrences (all)	0	0	7
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 14 (21.43%)
occurrences (all)	0	1	4
Cheilitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gingival oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Proctitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	6
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	5 / 14 (35.71%)
occurrences (all)	1	1	11
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	5 / 14 (35.71%)
occurrences (all)	0	0	9
Dry mouth			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	4 / 14 (28.57%)
occurrences (all)	2	1	4
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bile duct stenosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hepatic pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 14 (21.43%)
occurrences (all)	0	1	3
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Itching scar			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Nail bed disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nail hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	3
Palmoplantar keratoderma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bladder prolapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	6
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Bronchitis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Oesophageal candidiasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Pelvic abscess subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Stoma site infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Metabolism and nutrition disorders			
Calciphylaxis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	2 / 5 (40.00%) 3	1 / 14 (7.14%) 1
Dehydration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 14 (7.14%) 1
Hyperphosphataemia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	2 / 5 (40.00%) 2	9 / 14 (64.29%) 11
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 14 (0.00%) 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hyponatraemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase 1: Dose Escalation: QD Dosing: 20 mg	Phase 1: Dose Escalation: QD Dosing: 24 mg	Phase 1: Dose Expansion Cohort 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	14 / 14 (100.00%)	57 / 57 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Infected neoplasm subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Vascular disorders			
Hot flush subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4	1 / 14 (7.14%) 1	4 / 57 (7.02%) 7
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 14 (14.29%) 2	7 / 57 (12.28%) 10
Chills subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	3 / 57 (5.26%) 4
Fatigue			

subjects affected / exposed	1 / 7 (14.29%)	2 / 14 (14.29%)	12 / 57 (21.05%)
occurrences (all)	1	3	14
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Mucosal dryness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	8 / 57 (14.04%)
occurrences (all)	0	1	8
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	4 / 57 (7.02%)
occurrences (all)	1	1	5
Xerosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Device failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	2 / 7 (28.57%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	2	1	0
Face oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Reproductive system and breast disorders Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 4
Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Breast ulceration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Ovarian vein thrombosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 14 (7.14%) 1	0 / 57 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 14 (7.14%) 1	0 / 57 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Acute pulmonary oedema subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Cough			

subjects affected / exposed	0 / 7 (0.00%)	2 / 14 (14.29%)	3 / 57 (5.26%)
occurrences (all)	0	2	3
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	4
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	0	1	3
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	1	0	1
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Pleurisy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1

Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	5 / 57 (8.77%)
occurrences (all)	0	1	6
Onychophagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)	5 / 14 (35.71%)	16 / 57 (28.07%)
occurrences (all)	4	11	33
Bilirubin conjugated increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	8 / 57 (14.04%)
occurrences (all)	0	1	19
Blood bilirubin increased			
subjects affected / exposed	1 / 7 (14.29%)	2 / 14 (14.29%)	9 / 57 (15.79%)
occurrences (all)	1	6	19
Blood calcium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	4
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	9 / 57 (15.79%)
occurrences (all)	0	1	14
Blood phosphorus increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	10
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	1	0	4
International normalised ratio increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	1	0	4
Troponin T increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	10 / 57 (17.54%)
occurrences (all)	0	1	15
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Gastric pH decreased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Burn oesophageal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Wound decomposition			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	7 / 57 (12.28%)
occurrences (all)	0	1	9
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 14 (21.43%)	7 / 57 (12.28%)
occurrences (all)	0	3	8
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	5 / 57 (8.77%)
occurrences (all)	0	0	12
Hemiparesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	5
Memory impairment			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	0	1	3
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 14 (14.29%)	2 / 57 (3.51%)
occurrences (all)	0	2	3
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	5
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	2
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Ataxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Partial seizures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 7 (42.86%)	3 / 14 (21.43%)	10 / 57 (17.54%)
occurrences (all)	3	7	14
Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences (all)	0	1	1
Thrombocytopenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	2	1	3

Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Lymphadenopathy mediastinal subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Ear and labyrinth disorders			
Hypacusis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Tinnitus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Vertigo subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	8 / 57 (14.04%) 16
Cataract nuclear subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Cataract subcapsular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Chorioretinopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Dry eye			

subjects affected / exposed	0 / 7 (0.00%)	2 / 14 (14.29%)	7 / 57 (12.28%)
occurrences (all)	0	2	7
Eye irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Keratitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	3
Lacrimation decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Optic nerve cupping			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Ocular hyperaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Retinal detachment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	8 / 57 (14.04%)
occurrences (all)	1	1	8
Visual impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Vitreous detachment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	5 / 14 (35.71%)	21 / 57 (36.84%)
occurrences (all)	1	10	30

Oesophageal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences (all)	0	1	1
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 7 (14.29%)	3 / 14 (21.43%)	13 / 57 (22.81%)
occurrences (all)	1	5	28
Vomiting			
subjects affected / exposed	2 / 7 (28.57%)	5 / 14 (35.71%)	15 / 57 (26.32%)
occurrences (all)	4	7	31
Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Colonic pseudo-obstruction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Gingival oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0

Glossodynia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	2 / 14 (14.29%)	3 / 57 (5.26%)
occurrences (all)	1	2	3
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	15 / 57 (26.32%)
occurrences (all)	1	1	22
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Anal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	4
Constipation			
subjects affected / exposed	3 / 7 (42.86%)	7 / 14 (50.00%)	18 / 57 (31.58%)
occurrences (all)	4	10	25
Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	7 / 14 (50.00%)	17 / 57 (29.82%)
occurrences (all)	3	10	19
Dry mouth			
subjects affected / exposed	1 / 7 (14.29%)	3 / 14 (21.43%)	13 / 57 (22.81%)
occurrences (all)	1	3	15
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	4

Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 7 (14.29%)	2 / 14 (14.29%)	7 / 57 (12.28%)
occurrences (all)	1	2	11
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	1	0	1
Lip swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	4 / 57 (7.02%)
occurrences (all)	1	1	8
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	6
Bile duct stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 14 (21.43%)	18 / 57 (31.58%)
occurrences (all)	1	3	23
Blister			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	2 / 14 (14.29%)	11 / 57 (19.30%)
occurrences (all)	0	2	11
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Hypertrichosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1

Itching scar			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	4
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	2 / 14 (14.29%)	3 / 57 (5.26%)
occurrences (all)	0	2	5
Nail hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Nail ridging			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	1	1	0
Onychalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	0	1	8
Onycholysis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	6 / 57 (10.53%)
occurrences (all)	0	1	9
Onychomadesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	5
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	15 / 57 (26.32%)
occurrences (all)	0	2	38
Palmoplantar keratoderma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Papule			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	4
Skin hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	4
Swelling face			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rash macular			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Bladder prolapse			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	2
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	10 / 57 (17.54%)
occurrences (all)	0	0	20
Bone pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	2 / 57 (3.51%)
occurrences (all)	0	1	2
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	8
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	1	1	10
Tendonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 14 (7.14%)	6 / 57 (10.53%)
occurrences (all)	2	1	8
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	5 / 57 (8.77%)
occurrences (all)	0	1	8
Musculoskeletal stiffness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	0	1	3
Cellulitis staphylococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	2 / 57 (3.51%)
occurrences (all)	0	1	2
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis viral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	8
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1

Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 14 (7.14%) 1	4 / 57 (7.02%) 4
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	5 / 57 (8.77%) 9
Urosepsis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Pneumonia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Localised infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Onychomycosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Oral fungal infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 14 (7.14%) 1	0 / 57 (0.00%) 0

Bronchitis viral subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 14 (7.14%) 1	0 / 57 (0.00%) 0
Oesophageal candidiasis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Pelvic abscess subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Stoma site infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Metabolism and nutrition disorders			
Calciphylaxis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	0 / 57 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 14 (21.43%) 3	10 / 57 (17.54%) 11
Dehydration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 1
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	12 / 57 (21.05%) 19
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	3 / 57 (5.26%) 5
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0	1 / 57 (1.75%) 3
Hyperphosphataemia subjects affected / exposed occurrences (all)	6 / 7 (85.71%) 7	12 / 14 (85.71%) 33	48 / 57 (84.21%) 220
Hyperuricaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences (all)	0	1	1
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	6 / 57 (10.53%)
occurrences (all)	0	0	6
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 14 (7.14%)	1 / 57 (1.75%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 14 (7.14%)	3 / 57 (5.26%)
occurrences (all)	2	1	4
Hypophosphataemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 14 (0.00%)	10 / 57 (17.54%)
occurrences (all)	1	0	22
Hypovolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 14 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Expansion: Cohort 2	Phase 1: Dose Expansion: Cohort 3	Phase 1: Dose Expansion: Cohort 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 34 (100.00%)	15 / 15 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cancer pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Skin papilloma subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Tumour pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 15 (6.67%) 1	2 / 13 (15.38%) 3
Infected neoplasm subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Vascular disorders Hot flush subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 15 (6.67%) 2	0 / 13 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	1 / 15 (6.67%) 1	0 / 13 (0.00%) 0
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	7 / 34 (20.59%) 15	2 / 15 (13.33%) 2	0 / 13 (0.00%) 0
Chills			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	9 / 34 (26.47%)	4 / 15 (26.67%)	6 / 13 (46.15%)
occurrences (all)	12	5	6
Influenza like illness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 34 (0.00%)	3 / 15 (20.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
Pain			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Peripheral swelling			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Xerosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Device failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Face oedema			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal dryness			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Breast ulceration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ovarian vein thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Acute pulmonary oedema			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	3
Dyspnoea exertional			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Hiccups			
subjects affected / exposed	2 / 34 (5.88%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
Hypoxia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	3 / 34 (8.82%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Pleural effusion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Pulmonary embolism			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Confusional state			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Onychophagia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 34 (23.53%)	2 / 15 (13.33%)	5 / 13 (38.46%)
occurrences (all)	14	3	11
Bilirubin conjugated increased			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 34 (8.82%)	2 / 15 (13.33%)	2 / 13 (15.38%)
occurrences (all)	3	2	2
Blood bilirubin increased			
subjects affected / exposed	2 / 34 (5.88%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
Blood calcium increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 34 (5.88%)	3 / 15 (20.00%)	1 / 13 (7.69%)
occurrences (all)	4	8	3
Blood phosphorus increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 34 (8.82%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Neutrophil count decreased			

subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Troponin T increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 34 (0.00%)	2 / 15 (13.33%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Weight decreased			
subjects affected / exposed	2 / 34 (5.88%)	2 / 15 (13.33%)	1 / 13 (7.69%)
occurrences (all)	2	3	2
Weight increased			
subjects affected / exposed	3 / 34 (8.82%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastric pH decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Accidental overdose			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Wound decomposition subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 15 (6.67%) 1	0 / 13 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Dysgeusia subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	2 / 15 (13.33%) 4	0 / 13 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	6 / 34 (17.65%) 6	2 / 15 (13.33%) 2	1 / 13 (7.69%) 1
Hemiparesis			

subjects affected / exposed	4 / 34 (11.76%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	6	0	0
Hypoaesthesia			
subjects affected / exposed	4 / 34 (11.76%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Memory impairment			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Paraesthesia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Seizure			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Taste disorder			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Tremor			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 34 (11.76%)	2 / 15 (13.33%)	3 / 13 (23.08%)
occurrences (all)	4	2	9
Iron deficiency anaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	4

Neutropenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Vertigo			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Cerumen impaction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	3
Cataract nuclear			
subjects affected / exposed	0 / 34 (0.00%)	2 / 15 (13.33%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Cataract subcapsular			

subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Chorioretinopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Eye irritation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Growth of eyelashes			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Keratitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lacrimation decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Optic nerve cupping			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Ocular surface disease			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pinguecula			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Trichiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Xerophthalmia			

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 34 (11.76%)	3 / 15 (20.00%)	4 / 13 (30.77%)
occurrences (all)	5	3	4
Oesophageal pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Rectal haemorrhage			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Stomatitis			
subjects affected / exposed	3 / 34 (8.82%)	3 / 15 (20.00%)	2 / 13 (15.38%)
occurrences (all)	3	3	5
Vomiting			
subjects affected / exposed	10 / 34 (29.41%)	1 / 15 (6.67%)	3 / 13 (23.08%)
occurrences (all)	14	2	3
Cheilitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Colonic pseudo-obstruction subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Gingival oedema subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Glossodynia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Proctitis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Abdominal distension subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	5 / 34 (14.71%) 5	3 / 15 (20.00%) 3	1 / 13 (7.69%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Anal inflammation subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	0 / 13 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	1 / 13 (7.69%) 1
Constipation subjects affected / exposed occurrences (all)	9 / 34 (26.47%) 11	6 / 15 (40.00%) 10	3 / 13 (23.08%) 4
Diarrhoea subjects affected / exposed occurrences (all)	13 / 34 (38.24%) 16	4 / 15 (26.67%) 7	3 / 13 (23.08%) 4

Dry mouth			
subjects affected / exposed	4 / 34 (11.76%)	3 / 15 (20.00%)	1 / 13 (7.69%)
occurrences (all)	4	4	1
Dyspepsia			
subjects affected / exposed	3 / 34 (8.82%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
Dysphagia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Flatulence			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	2
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 34 (5.88%)	2 / 15 (13.33%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Lip swelling			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Bile duct stenosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 34 (14.71%)	3 / 15 (20.00%)	0 / 13 (0.00%)
occurrences (all)	7	3	0
Blister			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	2 / 34 (5.88%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
Erythema			

subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypertrichosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Itching scar			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Nail disorder			
subjects affected / exposed	0 / 34 (0.00%)	2 / 15 (13.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Nail hypertrophy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Nail ridging			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Onychalgia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Onycholysis			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Onychomadesis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	2 / 34 (5.88%)	3 / 15 (20.00%)	1 / 13 (7.69%)
occurrences (all)	4	5	1

Palmoplantar keratoderma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Plantar erythema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Skin hypertrophy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Xeroderma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Skin fissures			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Bladder prolapse			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Haematuria			
subjects affected / exposed	0 / 34 (0.00%)	2 / 15 (13.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Pollakiuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Renal failure			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Micturition disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	3 / 34 (8.82%)	1 / 15 (6.67%)	2 / 13 (15.38%)
occurrences (all)	5	1	3
Bone pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	4 / 34 (11.76%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	5	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Myalgia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Tendonitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Osteolysis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Muscle spasms			
subjects affected / exposed	3 / 34 (8.82%)	2 / 15 (13.33%)	1 / 13 (7.69%)
occurrences (all)	3	3	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Cellulitis staphylococcal			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Conjunctivitis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Cystitis			

subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Device related infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
Pharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 34 (5.88%)	3 / 15 (20.00%)	0 / 13 (0.00%)
occurrences (all)	3	4	0
Urosepsis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pelvic abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Calciphylaxis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	6 / 34 (17.65%)	4 / 15 (26.67%)	1 / 13 (7.69%)
occurrences (all)	6	7	1
Dehydration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	2 / 34 (5.88%)	2 / 15 (13.33%)	2 / 13 (15.38%)
occurrences (all)	5	3	3
Hyperglycaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Hyperphosphataemia			
subjects affected / exposed	30 / 34 (88.24%)	9 / 15 (60.00%)	12 / 13 (92.31%)
occurrences (all)	108	22	36
Hyperuricaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	4	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	2 / 13 (15.38%)
occurrences (all)	2	1	3
Hypophosphataemia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 15 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	3
Hypovolaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Failure to thrive			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Expansion: Cohort 5	Phase 1: Dose Expansion: Cohort 6	Phase 1: Dose Expansion: Sub- cohort 2
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	23 / 24 (95.83%)	26 / 27 (96.30%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Skin papilloma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tumour haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Infected neoplasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Phlebitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	4 / 24 (16.67%)	6 / 27 (22.22%)	1 / 8 (12.50%)
occurrences (all)	4	9	0
Chills			
subjects affected / exposed	0 / 24 (0.00%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	6	0
Fatigue			
subjects affected / exposed	8 / 24 (33.33%)	9 / 27 (33.33%)	2 / 8 (25.00%)
occurrences (all)	18	15	2
Influenza like illness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	2 / 24 (8.33%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	3	2	0
Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 24 (8.33%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Xerosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Disease progression subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Face oedema subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Gait disturbance subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Vulvovaginal dryness subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Breast ulceration subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Ovarian vein thrombosis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Vaginal haemorrhage			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 24 (8.33%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Dysphonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	5 / 24 (20.83%)	4 / 27 (14.81%)	0 / 8 (0.00%)
occurrences (all)	5	6	0
Dyspnoea exertional			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pneumothorax			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal dysplasia			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 27 (3.70%) 1	0 / 8 (0.00%) 0
Confusional state			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	2 / 8 (25.00%) 2
Insomnia			
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 3	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Onychophagia			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	1 / 8 (12.50%) 1
Agitation			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Delirium			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Depression			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Hallucination			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Libido decreased			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Aspartate aminotransferase increased			

subjects affected / exposed	6 / 24 (25.00%)	9 / 27 (33.33%)	0 / 8 (0.00%)
occurrences (all)	18	13	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Blood albumin decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 24 (8.33%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	4	6	0
Blood bilirubin increased			
subjects affected / exposed	2 / 24 (8.33%)	1 / 27 (3.70%)	1 / 8 (12.50%)
occurrences (all)	5	4	2
Blood calcium increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	3 / 24 (12.50%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	3	4	0
Blood phosphorus increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Troponin T increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	4 / 24 (16.67%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	5	1	0
Weight increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastric pH decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Accidental overdose			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Burn oesophageal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post procedural oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Wound decomposition subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 27 (3.70%) 1	0 / 8 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 27 (3.70%) 1	0 / 8 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 27 (3.70%) 1	0 / 8 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3	3 / 27 (11.11%) 4	0 / 8 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 4	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Hemiparesis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Tremor			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 24 (16.67%)	5 / 27 (18.52%)	1 / 8 (12.50%)
occurrences (all)	10	7	4
Iron deficiency anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Thrombocytopenia			
subjects affected / exposed	2 / 24 (8.33%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Increased tendency to bruise			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Vertigo			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cerumen impaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	2 / 24 (8.33%)	2 / 27 (7.41%)	1 / 8 (12.50%)
occurrences (all)	3	3	1
Cataract nuclear			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cataract subcapsular			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	3 / 24 (12.50%)	5 / 27 (18.52%)	0 / 8 (0.00%)
occurrences (all)	4	5	0
Eye irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Lacrimation decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Optic nerve cupping			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	1 / 8 (12.50%)
occurrences (all)	1	1	2
Retinal detachment			
subjects affected / exposed	2 / 24 (8.33%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	4	2	0
Subretinal fluid			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Visual impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	7 / 24 (29.17%)	13 / 27 (48.15%)	3 / 8 (37.50%)
occurrences (all)	7	20	3
Oesophageal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	4 / 24 (16.67%)	2 / 27 (7.41%)	1 / 8 (12.50%)
occurrences (all)	10	2	2
Vomiting			
subjects affected / exposed	5 / 24 (20.83%)	8 / 27 (29.63%)	0 / 8 (0.00%)
occurrences (all)	12	13	0
Cheilitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Colonic pseudo-obstruction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Gingival oedema subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Glossodynia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Proctitis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	2 / 27 (7.41%) 2	0 / 8 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 9	3 / 27 (11.11%) 3	0 / 8 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 27 (3.70%) 1	0 / 8 (0.00%) 0
Anal inflammation subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 27 (0.00%) 0	0 / 8 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	9 / 24 (37.50%) 12	11 / 27 (40.74%) 15	1 / 8 (12.50%) 2
Diarrhoea subjects affected / exposed occurrences (all)	11 / 24 (45.83%) 17	10 / 27 (37.04%) 14	5 / 8 (62.50%) 7

Dry mouth			
subjects affected / exposed	3 / 24 (12.50%)	7 / 27 (25.93%)	0 / 8 (0.00%)
occurrences (all)	3	7	0
Dyspepsia			
subjects affected / exposed	1 / 24 (4.17%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	2	3	0
Dysphagia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 24 (12.50%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	5	2	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lip swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 24 (0.00%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Intestinal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Bile duct stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 24 (20.83%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	5	2	0
Blister			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	3 / 24 (12.50%)	4 / 27 (14.81%)	0 / 8 (0.00%)
occurrences (all)	3	5	0
Erythema			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Itching scar			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nail disorder			
subjects affected / exposed	3 / 24 (12.50%)	3 / 27 (11.11%)	1 / 8 (12.50%)
occurrences (all)	7	3	1
Nail hypertrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Onychalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	3 / 24 (12.50%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	3	2	0
Onychomadesis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	1 / 8 (12.50%)
occurrences (all)	8	2	1

Palmoplantar keratoderma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Rash			
subjects affected / exposed	2 / 24 (8.33%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Skin hypertrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Xeroderma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Skin fissures			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Bladder prolapse			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Haematuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 24 (8.33%)	2 / 27 (7.41%)	1 / 8 (12.50%)
occurrences (all)	2	2	1
Bone pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	2 / 24 (8.33%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 24 (4.17%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Tendonitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Dactylitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Osteolysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 24 (8.33%)	1 / 27 (3.70%)	1 / 8 (12.50%)
occurrences (all)	3	1	2
Muscle spasms			
subjects affected / exposed	1 / 24 (4.17%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cystitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Lung infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Oral candidiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	2 / 24 (8.33%)	3 / 27 (11.11%)	2 / 8 (25.00%)
occurrences (all)	2	5	3
Urosepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Calciphylaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	7 / 24 (29.17%)	6 / 27 (22.22%)	1 / 8 (12.50%)
occurrences (all)	12	8	1
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypercalcaemia			
subjects affected / exposed	1 / 24 (4.17%)	4 / 27 (14.81%)	0 / 8 (0.00%)
occurrences (all)	2	6	0
Hyperglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 27 (7.41%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Hyperkalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hyperphosphataemia			
subjects affected / exposed	19 / 24 (79.17%)	21 / 27 (77.78%)	5 / 8 (62.50%)
occurrences (all)	74	58	19
Hyperuricaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)	3 / 27 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Hypomagnesaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 27 (3.70%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypophosphataemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Hypovolaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 27 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Dose Expansion: Sub-cohort 1	Phase 2	
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	19 / 19 (100.00%)	103 / 103 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Skin papilloma			
subjects affected / exposed	2 / 19 (10.53%)	2 / 103 (1.94%)	
occurrences (all)	2	2	
Tumour haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Tumour pain			
subjects affected / exposed	0 / 19 (0.00%)	5 / 103 (4.85%)	
occurrences (all)	0	5	
Infected neoplasm			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)	6 / 103 (5.83%)	
occurrences (all)	0	19	
Phlebitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Venous thrombosis limb			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	4 / 19 (21.05%)	4 / 103 (3.88%)	
occurrences (all)	6	6	
General disorders and administration site conditions			

Asthenia		
subjects affected / exposed	1 / 19 (5.26%)	4 / 103 (3.88%)
occurrences (all)	3	7
Chills		
subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)
occurrences (all)	0	5
Fatigue		
subjects affected / exposed	4 / 19 (21.05%)	36 / 103 (34.95%)
occurrences (all)	5	65
Influenza like illness		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Mucosal dryness		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Non-cardiac chest pain		
subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)
occurrences (all)	0	4
Oedema peripheral		
subjects affected / exposed	3 / 19 (15.79%)	15 / 103 (14.56%)
occurrences (all)	3	17
Pain		
subjects affected / exposed	1 / 19 (5.26%)	3 / 103 (2.91%)
occurrences (all)	1	3
Peripheral swelling		
subjects affected / exposed	2 / 19 (10.53%)	2 / 103 (1.94%)
occurrences (all)	2	2
Pyrexia		
subjects affected / exposed	3 / 19 (15.79%)	11 / 103 (10.68%)
occurrences (all)	3	15
Xerosis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Device failure		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Disease progression subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Face oedema subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Gait disturbance subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Malaise subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Chest discomfort subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Chest pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Pelvic pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	1 / 103 (0.97%) 1	
Vulvovaginal dryness subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 103 (0.00%) 0	
Breast ulceration subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Ovarian vein thrombosis subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Vaginal haemorrhage			

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Cough subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2	4 / 103 (3.88%) 4	
Dysphonia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 103 (0.97%) 1	
Dyspnoea subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	4 / 103 (3.88%) 6	
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Epistaxis subjects affected / exposed occurrences (all)	4 / 19 (21.05%) 4	7 / 103 (6.80%) 8	
Hiccups subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	3 / 103 (2.91%) 3	
Hypoxia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Nasal congestion subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	4 / 103 (3.88%) 6	
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2	10 / 103 (9.71%) 10	
Pleural effusion			

subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Pneumothorax		
subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)
occurrences (all)	1	2
Pulmonary embolism		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Rhinitis allergic		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Throat irritation		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Upper-airway cough syndrome		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Dry throat		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Haemoptysis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Hypoventilation		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Nasal dryness		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Pleurisy		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Rhinalgia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Oropharyngeal dysplasia		

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	2 / 103 (1.94%) 2	
Confusional state			
subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	5 / 103 (4.85%) 5	
Insomnia			
subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 4	8 / 103 (7.77%) 9	
Onychophagia			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Agitation			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Delirium			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Depression			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Hallucination			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Libido decreased			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	3 / 103 (2.91%) 3	
Aspartate aminotransferase increased			

subjects affected / exposed	7 / 19 (36.84%)	26 / 103 (25.24%)
occurrences (all)	11	60
Bilirubin conjugated increased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Blood albumin decreased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Blood alkaline phosphatase increased		
subjects affected / exposed	4 / 19 (21.05%)	13 / 103 (12.62%)
occurrences (all)	7	25
Blood bilirubin increased		
subjects affected / exposed	1 / 19 (5.26%)	7 / 103 (6.80%)
occurrences (all)	2	20
Blood calcium increased		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	2	1
Blood creatine phosphokinase increased		
subjects affected / exposed	3 / 19 (15.79%)	10 / 103 (9.71%)
occurrences (all)	3	12
Blood creatinine increased		
subjects affected / exposed	5 / 19 (26.32%)	15 / 103 (14.56%)
occurrences (all)	8	30
Blood phosphorus increased		
subjects affected / exposed	0 / 19 (0.00%)	9 / 103 (8.74%)
occurrences (all)	0	30
Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	4
International normalised ratio increased		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Lymphocyte count decreased		

subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)
occurrences (all)	0	9
Neutrophil count decreased		
subjects affected / exposed	2 / 19 (10.53%)	6 / 103 (5.83%)
occurrences (all)	2	6
Platelet count decreased		
subjects affected / exposed	2 / 19 (10.53%)	3 / 103 (2.91%)
occurrences (all)	7	6
Troponin T increased		
subjects affected / exposed	0 / 19 (0.00%)	7 / 103 (6.80%)
occurrences (all)	0	8
Urine analysis abnormal		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Weight decreased		
subjects affected / exposed	3 / 19 (15.79%)	19 / 103 (18.45%)
occurrences (all)	5	29
Weight increased		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	4
White blood cell count decreased		
subjects affected / exposed	1 / 19 (5.26%)	6 / 103 (5.83%)
occurrences (all)	2	6
Lipase increased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Platelet count increased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Amylase increased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Blood creatine phosphokinase decreased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Gastric pH decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Accidental overdose			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Burn oesophageal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Muscle rupture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Post procedural oedema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Stoma site pain			

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Wound decomposition subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 3	0 / 103 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	2 / 103 (1.94%) 2	
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	1 / 103 (0.97%) 1	
Balance disorder subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Dizziness subjects affected / exposed occurrences (all)	5 / 19 (26.32%) 7	10 / 103 (9.71%) 11	
Dysgeusia subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 3	21 / 103 (20.39%) 27	
Headache subjects affected / exposed occurrences (all)	4 / 19 (21.05%) 6	8 / 103 (7.77%) 13	
Hemiparesis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Hypoaesthesia		
subjects affected / exposed	1 / 19 (5.26%)	7 / 103 (6.80%)
occurrences (all)	1	9
Memory impairment		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Neuropathy peripheral		
subjects affected / exposed	0 / 19 (0.00%)	6 / 103 (5.83%)
occurrences (all)	0	7
Paraesthesia		
subjects affected / exposed	0 / 19 (0.00%)	5 / 103 (4.85%)
occurrences (all)	0	6
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 19 (0.00%)	10 / 103 (9.71%)
occurrences (all)	0	15
Seizure		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Taste disorder		
subjects affected / exposed	0 / 19 (0.00%)	4 / 103 (3.88%)
occurrences (all)	0	4
Tremor		
subjects affected / exposed	1 / 19 (5.26%)	3 / 103 (2.91%)
occurrences (all)	1	3
Cognitive disorder		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Aphasia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Ataxia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Disturbance in attention		

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Dysarthria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Encephalopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Migraine with aura			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Partial seizures			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Nervous system disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Peroneal nerve palsy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)	
occurrences (all)	1	3	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 19 (10.53%)	17 / 103 (16.50%)	
occurrences (all)	2	36	
Iron deficiency anaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	1 / 19 (5.26%)	4 / 103 (3.88%)	
occurrences (all)	2	5	

Neutropenia			
subjects affected / exposed	1 / 19 (5.26%)	4 / 103 (3.88%)	
occurrences (all)	1	6	
Thrombocytopenia			
subjects affected / exposed	1 / 19 (5.26%)	12 / 103 (11.65%)	
occurrences (all)	1	27	
Increased tendency to bruise			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Lymph node pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Tinnitus			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences (all)	0	4	
Cerumen impaction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			
subjects affected / exposed	1 / 19 (5.26%)	6 / 103 (5.83%)	
occurrences (all)	8	6	
Cataract nuclear			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Cataract subcapsular			

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Chorioretinopathy		
subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)
occurrences (all)	1	2
Dry eye		
subjects affected / exposed	2 / 19 (10.53%)	23 / 103 (22.33%)
occurrences (all)	2	28
Eye irritation		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Eye pain		
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)
occurrences (all)	0	5
Growth of eyelashes		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Keratitis		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Lacrimation decreased		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Optic nerve cupping		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Photopsia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Visual acuity reduced		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Vitreous adhesions		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Vitreous floaters		

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Lacrimation increased		
subjects affected / exposed	1 / 19 (5.26%)	6 / 103 (5.83%)
occurrences (all)	1	6
Ocular hyperaemia		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Ocular surface disease		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Pinguecula		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Punctate keratitis		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	1	5
Retinal detachment		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Subretinal fluid		
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)
occurrences (all)	0	3
Trichiasis		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Vision blurred		
subjects affected / exposed	4 / 19 (21.05%)	8 / 103 (7.77%)
occurrences (all)	4	9
Visual impairment		
subjects affected / exposed	1 / 19 (5.26%)	4 / 103 (3.88%)
occurrences (all)	1	4
Vitreous detachment		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Xerophthalmia		

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	8 / 19 (42.11%)	25 / 103 (24.27%)	
occurrences (all)	11	38	
Oesophageal pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Oral pain			
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)	
occurrences (all)	0	4	
Rectal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	7 / 19 (36.84%)	25 / 103 (24.27%)	
occurrences (all)	7	56	
Vomiting			
subjects affected / exposed	4 / 19 (21.05%)	20 / 103 (19.42%)	
occurrences (all)	5	30	
Cheilitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Epigastric discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Haematemesis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Oesophagitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Proctalgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	

Colonic pseudo-obstruction subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0
Gingival oedema subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0
Glossodynia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0
Proctitis subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 103 (0.97%) 1
Abdominal distension subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2	6 / 103 (5.83%) 6
Abdominal pain subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2	21 / 103 (20.39%) 28
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 103 (0.00%) 0
Anal inflammation subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 103 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 4	4 / 103 (3.88%) 5
Constipation subjects affected / exposed occurrences (all)	8 / 19 (42.11%) 10	40 / 103 (38.83%) 50
Diarrhoea subjects affected / exposed occurrences (all)	5 / 19 (26.32%) 7	37 / 103 (35.92%) 65

Dry mouth		
subjects affected / exposed	7 / 19 (36.84%)	36 / 103 (34.95%)
occurrences (all)	7	41
Dyspepsia		
subjects affected / exposed	3 / 19 (15.79%)	7 / 103 (6.80%)
occurrences (all)	4	8
Dysphagia		
subjects affected / exposed	0 / 19 (0.00%)	5 / 103 (4.85%)
occurrences (all)	0	5
Flatulence		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Gastrointestinal haemorrhage		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 19 (5.26%)	6 / 103 (5.83%)
occurrences (all)	1	8
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Haemorrhoids		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	2
Lip swelling		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Mouth ulceration		
subjects affected / exposed	1 / 19 (5.26%)	4 / 103 (3.88%)
occurrences (all)	1	4
Abdominal pain upper		
subjects affected / exposed	3 / 19 (15.79%)	8 / 103 (7.77%)
occurrences (all)	3	10
Intestinal obstruction		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)	
occurrences (all)	0	5	
Bile duct stenosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Bile duct obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Hepatic pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 19 (5.26%)	35 / 103 (33.98%)	
occurrences (all)	3	41	
Blister			
subjects affected / exposed	2 / 19 (10.53%)	1 / 103 (0.97%)	
occurrences (all)	2	1	
Decubitus ulcer			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Dermatitis contact			
subjects affected / exposed	2 / 19 (10.53%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Dry skin			
subjects affected / exposed	7 / 19 (36.84%)	30 / 103 (29.13%)	
occurrences (all)	7	39	
Erythema			

subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Hypertrichosis		
subjects affected / exposed	3 / 19 (15.79%)	1 / 103 (0.97%)
occurrences (all)	3	1
Itching scar		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Nail bed disorder		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Nail discolouration		
subjects affected / exposed	2 / 19 (10.53%)	14 / 103 (13.59%)
occurrences (all)	2	20
Nail disorder		
subjects affected / exposed	1 / 19 (5.26%)	16 / 103 (15.53%)
occurrences (all)	1	20
Nail hypertrophy		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Nail ridging		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Onychalgia		
subjects affected / exposed	1 / 19 (5.26%)	3 / 103 (2.91%)
occurrences (all)	1	3
Onycholysis		
subjects affected / exposed	3 / 19 (15.79%)	16 / 103 (15.53%)
occurrences (all)	3	24
Onychomadesis		
subjects affected / exposed	2 / 19 (10.53%)	15 / 103 (14.56%)
occurrences (all)	3	19
Palmar-plantar erythrodysaesthesia syndrome		
subjects affected / exposed	6 / 19 (31.58%)	22 / 103 (21.36%)
occurrences (all)	19	87

Palmoplantar keratoderma		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Papule		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Plantar erythema		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Pruritus		
subjects affected / exposed	1 / 19 (5.26%)	9 / 103 (8.74%)
occurrences (all)	1	12
Rash		
subjects affected / exposed	3 / 19 (15.79%)	5 / 103 (4.85%)
occurrences (all)	5	6
Rash maculo-papular		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	4
Skin hypertrophy		
subjects affected / exposed	2 / 19 (10.53%)	0 / 103 (0.00%)
occurrences (all)	2	0
Skin mass		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Swelling face		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Xeroderma		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Skin ulcer		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Skin haemorrhage		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Skin fissures		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Rash macular		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Night sweats		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Nail dystrophy		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Nail bed tenderness		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Onychoclasia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Pain of skin		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Urticaria		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Urticaria contact		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Hyperhidrosis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Skin exfoliation		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Dermatitis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)	
occurrences (all)	1	1	
Bladder prolapse			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Dysuria			
subjects affected / exposed	0 / 19 (0.00%)	5 / 103 (4.85%)	
occurrences (all)	0	5	
Haematuria			
subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)	
occurrences (all)	1	3	
Pollakiuria			
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)	
occurrences (all)	1	3	
Proteinuria			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	4	
Renal failure			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Urinary retention			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Micturition disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Hypopituitarism			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Arthralgia		
subjects affected / exposed	3 / 19 (15.79%)	23 / 103 (22.33%)
occurrences (all)	3	32
Bone pain		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Joint swelling		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	2
Muscular weakness		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	3
Musculoskeletal chest pain		
subjects affected / exposed	2 / 19 (10.53%)	2 / 103 (1.94%)
occurrences (all)	2	2
Musculoskeletal pain		
subjects affected / exposed	3 / 19 (15.79%)	6 / 103 (5.83%)
occurrences (all)	3	8
Myalgia		
subjects affected / exposed	0 / 19 (0.00%)	15 / 103 (14.56%)
occurrences (all)	0	24
Neck pain		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	2	1
Pain in extremity		
subjects affected / exposed	5 / 19 (26.32%)	9 / 103 (8.74%)
occurrences (all)	10	13
Tendonitis		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Dactylitis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Groin pain		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

Osteolysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	5 / 19 (26.32%)	17 / 103 (16.50%)	
occurrences (all)	6	21	
Muscle spasms			
subjects affected / exposed	2 / 19 (10.53%)	15 / 103 (14.56%)	
occurrences (all)	3	21	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)	
occurrences (all)	0	3	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	0 / 19 (0.00%)	3 / 103 (2.91%)	
occurrences (all)	0	3	
Cystitis			

subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Device related infection		
subjects affected / exposed	0 / 19 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Gastroenteritis viral		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Herpes zoster		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Influenza		
subjects affected / exposed	2 / 19 (10.53%)	0 / 103 (0.00%)
occurrences (all)	2	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Lung infection		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Oral candidiasis		
subjects affected / exposed	2 / 19 (10.53%)	2 / 103 (1.94%)
occurrences (all)	2	2
Otitis media		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Paronychia		
subjects affected / exposed	5 / 19 (26.32%)	8 / 103 (7.77%)
occurrences (all)	8	18
Pharyngitis		
subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)
occurrences (all)	1	2
Pharyngitis streptococcal		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Sinusitis		

subjects affected / exposed	1 / 19 (5.26%)	2 / 103 (1.94%)
occurrences (all)	1	2
Tooth infection		
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)
occurrences (all)	1	0
Upper respiratory tract infection		
subjects affected / exposed	1 / 19 (5.26%)	7 / 103 (6.80%)
occurrences (all)	1	7
Urinary tract infection		
subjects affected / exposed	6 / 19 (31.58%)	20 / 103 (19.42%)
occurrences (all)	7	23
Urosepsis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Vulvovaginal mycotic infection		
subjects affected / exposed	1 / 19 (5.26%)	1 / 103 (0.97%)
occurrences (all)	1	1
Pneumonia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Localised infection		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Onychomycosis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Sepsis		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Oral fungal infection		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Vaginal infection		

subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Bronchitis viral			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Pelvic abscess			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Stoma site infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Calciphylaxis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			
subjects affected / exposed	3 / 19 (15.79%)	23 / 103 (22.33%)	
occurrences (all)	4	51	
Dehydration			
subjects affected / exposed	2 / 19 (10.53%)	6 / 103 (5.83%)	
occurrences (all)	2	12	
Hypercalcaemia			
subjects affected / exposed	4 / 19 (21.05%)	16 / 103 (15.53%)	
occurrences (all)	6	30	
Hyperglycaemia			
subjects affected / exposed	2 / 19 (10.53%)	4 / 103 (3.88%)	
occurrences (all)	4	5	
Hyperkalaemia			
subjects affected / exposed	1 / 19 (5.26%)	3 / 103 (2.91%)	
occurrences (all)	3	5	

Hyperphosphataemia		
subjects affected / exposed	17 / 19 (89.47%)	88 / 103 (85.44%)
occurrences (all)	71	537
Hyperuricaemia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Hypoalbuminaemia		
subjects affected / exposed	0 / 19 (0.00%)	6 / 103 (5.83%)
occurrences (all)	0	15
Hypocalcaemia		
subjects affected / exposed	0 / 19 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	2
Hypokalaemia		
subjects affected / exposed	0 / 19 (0.00%)	6 / 103 (5.83%)
occurrences (all)	0	10
Hypomagnesaemia		
subjects affected / exposed	3 / 19 (15.79%)	3 / 103 (2.91%)
occurrences (all)	3	3
Hyponatraemia		
subjects affected / exposed	3 / 19 (15.79%)	17 / 103 (16.50%)
occurrences (all)	4	32
Hypophosphataemia		
subjects affected / exposed	2 / 19 (10.53%)	14 / 103 (13.59%)
occurrences (all)	2	21
Hypovolaemia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Failure to thrive		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0
Hypophagia		
subjects affected / exposed	0 / 19 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 January 2014	- Added language "who have failed all standard therapies or for whom standard therapy does not exist" in order to clarify study rationale, study objectives, study design, and inclusion criteria (Phase 1 Dose Escalation) - Revised "Definitions of Dose-limiting Toxicity and Maximum Tolerated Dose" criteria for hyperphosphatemia and increase of creatinine. - Revised inclusion criteria to include serum phosphorus and serum calcium - Revised exclusion criteria to include QT interval - Added information to management of hyperphosphatemia - Added ophthalmological examination visits per local requirement or as clinically indicated
22 September 2014	- Updated visit schedules in Table 1A and Table 1B (serum chemistry only) - Added information to the exclusion criteria for noninvestigational anticancer therapy - Expanded the list of concomitant medications and therapies - Revised "Definitions of Dose-limiting Toxicity and Maximum Tolerated Dose" criteria for hyperphosphatemia and creatinine increase. - Added serum phosphorus and serum calcium to inclusion criteria - Added information to the QT interval exclusion criteria - Clarified management of hyperphosphatemia - Revised dose reduction requirements - Clarified Screening criteria - Clarified fractionation of CK into isoforms - Clarified postdose blood sample collection (QOD and QD) pharmacokinetics (PK)/pharmacodynamic collection (Phase 1 Dose Escalation). - Clarified of postdose urine sample (QOD only) urine sample to pharmacodynamic urine sample collection (Phase 1 Dose Escalation). - Clarification of study phase to solid tumor assessments/scans - Expanded method of capturing and reporting medication errors.
19 February 2016	- Removed references to NSCLC, gastric, and breast cancers and multiple myeloma population from sections throughout the protocol amendment as appropriate - Added information to timing of initiating the QD arm in relation to QOD dosing schedule - Updated the language on women of childbearing potential and effective contraception inclusion criteria to comply with Clinical Trials Facilitation Group (CTFG) Guidelines - Added change to include tablets (i.e., number of tablets, description of packaging and storage information) about 4 mg and 20 mg TAS-120 tablets. - Updated information on assessment of overall response rate - Revised section on determination of sample size - Updated guidelines for management of hyperphosphatemia - Added additional electrocardiogram (ECG) evaluations as appropriate
15 May 2017	- Updated clinical information for 2 clinical trials TAS-120-101 Phase 1/2 Trial TPU-TAS-120-101 [US/EU/Australia] and Phase 1 trial 10059010 [Japan] - Added rationale for the selection of QD dosing schedule - Added a new intermediate dose level of 20 mg QD to enable a more precise determination of the Recommended Phase 2 Dose (RP2D)

29 August 2017	- Added specific cohorts of patients to be enrolled in the 4 groups in the Phase 1 Expansion - Updated study endpoints for the Phase 1 Expansion and Phase 2 parts of the study including early progression rate (EPR) as a primary endpoint and added Response Assessment in Neuro-Oncology (RANO) as the guidelines for efficacy assessment for patients with glioblastoma multiforme (GBM) or grade III glioma, PFS and OS. - Added efficacy and tumor assessments for brain tumors and added RANO tumor assessment criteria for brain tumors. - Updated the inclusion and exclusion criteria to further define patients included in Phase 1 Expansion and Phase 2 - Revised guidelines for serum phosphorus monitoring and management of hyperphosphatemia - Provided the procedure for screening and identifying ICCA patients with tumors that have FGFR gene fusions in the Phase 2 part of the study. - Added assessment of CA19-9 for cholangiocarcinoma patients - Clarification of evaluations at visit schedules - Updated definitions of populations in statistical methods in both the Phase 1 Expansion and Phase 2 - Revised section on determination of sample size to further specify the sample size justification for the specific cohorts of patients to be enrolled in the Phase 1 Expansion and to provide sample size justification for patients enrolled in the Phase 2 part of the study.
31 January 2018	- Added an additional 4 cohorts of patients to be enrolled in the Phase 1 Expansion. - Added information that established 20 mg QD as the RP2D - Clarified Phase 2 primary objective, added a key secondary objective, other secondary objectives and PK exploratory objective - Updated the inclusion and exclusion criteria to further define patients in Phase 1 Expansion and Phase 2 - Provided methods for prescreening testing of tumor samples for FGFR2 gene fusion before enrollment into Phase 2 - Removed TAS-120 capsule formulation as it is no longer applicable - Updated information on timing and fasting requirements to study drug administration procedures - Updated guidelines on Dose Hold, Dose Modifications and Dose Resumption - Clarification of evaluations in visit schedules - Updated information on statistical analysis of disease control rate (DCR), duration of response (DOR), PFS - Added assessments of and statistical analysis of Patient-Reported Outcome assessments. - Updated determination of sample size information to further specify the sample size justification for the specific cohorts of patients to be enrolled in the Phase 1 Expansion and to further specify sample size justification for patients enrolled in the Phase 2 part of the study.

28 September 2018	Global - Reformatted and clarified study events tables to ensure consistency throughout the protocol. - Altered inclusion requirement for bilirubin to allow for serum or plasma assessment of bilirubin and to include patients with Gilbert's syndrome and bilirubin up to 3 x upper limit of normal. - Clarified requirements for pregnancy testing of women of childbearing potential throughout the study. - Throughout the document, editorial changes, including elimination of errors or minor rewordings to improve clarity, were made as necessary. The administrative alterations do not affect the planned conduct or analysis of the study. Phase I Expansion - Added brief rationale for the design of the Phase I expansion portion of the study. - Enrollment suspended into Phase I expansion Groups 1, 3, 4, 6, and 8. - Refined criteria for enrollment into other groups in Phase I expansion, including: - o Changing the FGFR requirement for Group 7 from "FGF9 or FGF19 amplifications" to "FGFR2 amplifications." - o Changing the requirement for Group 5 from "grade III glioma" to "primary CNS tumors." - Changes were made to study objectives, statistical methods, and other sections of the protocol as necessary for consistency with the revised population of each subgroup in the Phase I expansion portion of the study. Phase 2 - Expanded eligibility requirements to allow all patients with FGFR2 rearrangements, rather than patients with FGFR2 gene fusions only. - Clarified requirements for tumor testing to determine and/or confirm study eligibility on the basis of FGR2 gene fusion status. - Clarified requirements for prior therapy (patients must have received at least one prior systemic gemcitabine-platinum therapy and have documented progression following the most recent prior therapy). - Added planned interim reviews of safety to be performed approximately every 3 months throughout the study, including brief description of the SRC that will perform these reviews
12 April 2019	- Guidelines for management of hyperphosphatemia were updated to reflect analysis of most current available data.
01 August 2019	- Requirement to have FGFR2 rearrangements be centrally confirmed prior to enrollment was removed. - Interim analysis was added.
12 February 2021	- Table of list of evaluations to be performed during Study Extension. - Clinical experience with TAS-120 was updated. - Added definition of study completion. - The drug interactions with TAS-120 have been updated. - Study Extension was added to allow patients still receiving benefits to continue to receive TAS-120 after the study is considered complete. - Supplemental Requirements for Japan Only: The anticipated date of study completion was amended from April 2021 to July 2021.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported