



Clinical trial results:

A Phase 1/2a Study of BMS-986179 Administered Alone and in Combination with Nivolumab (BMS-936558) in Subjects with Advanced Solid Tumors

Summary

EudraCT number	2016-000603-91
Trial protocol	NL DE IT
Global end of trial date	12 October 2021

Results information

Result version number	v1 (current)
This version publication date	28 October 2022
First version publication date	28 October 2022

Trial information

Trial identification

Sponsor protocol code	CA013-004
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02754141
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the safety and tolerability of BMS-986179 administered alone and in combination with nivolumab.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2016
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	Canada: 40
Country: Number of subjects enrolled	France: 75
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Italy: 18
Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Netherlands: 18
Country: Number of subjects enrolled	United States: 71
Worldwide total number of subjects	235
EEA total number of subjects	116

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)	140
From 65 to 84 years	94
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

235 participants treated

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
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Arm title	P1A 150mg
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Arm description:

BMS-986179 150mg monotherapy leading into BMS-986179 150mg + Nivo 240 combo therapy

Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

35mg/mL

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10mg/mL

Arm title	P1A 300mg
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Arm description:

BMS-986179 300mg monotherapy leading into BMS-986179 300mg + Nivo 240mg combo therapy

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10mg/mL

Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
35mg/mL

Arm title	P1A 600mg
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Arm description:

BMS-986179 600mg monotherapy leading into BMS-986179 600mg + Nivo 240mg combo therapy

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10mg/mL

Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

35mg/mL

Arm title	P1A 1200mg
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Arm description:

BMS-986179 1200mg monotherapy leading into BMS-986179 1200mg + Nivo 240mg combo therapy

Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

35mg/mL

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10mg/mL

Arm title	P1A 1600mg
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Arm description:

BMS-986179 1600mg monotherapy leading into BMS-986179 1600mg + Nivo 240mg combo therapy

Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P1B Combo Therapy 150mg
Arm description:	
BMS-986179 150mg + Nivo 360mg	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg
Arm description:	
BMS-986179 1200mg + Nivo 360mg	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Arm description:	
BMS-986179 1200mg + Nivo 480mg	
Arm type	Experimental

Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P1B BMS986-179 1600mg
Arm description:	
BMS-986179 1600mg SC	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Arm title	P2 Combo Pancreatic
Arm description:	
BMS-986179 1200mg Q2W + Nivo 240mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P2 Combo Therapy NSCLC
Arm description:	
BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Arm type	Experimental

Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P2 Combo Melanoma
Arm description:	
BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P2 Combo SCCHN
Arm description:	
BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P2 RCC Monotherapy

Arm description: BMS-986179 600mg Q2W monotherapy	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 35mg/mL	
Arm title	P2 RCC Combo Therapy
Arm description: BMS-986179 600mg Q2W + Nivo 480mg Q4W combo therapy	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 10mg/mL	
Arm title	P2 Combo Prostate
Arm description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 10mg/mL	
Arm title	P2 Combo Unassigned
Arm description: BMS-986179 1200mg Q2W + Nivo 240mg Q2W	
Arm type	Experimental

Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
10mg/mL	
Arm title	P2 Monotherapy Unassigned
Arm description:	
BMS-986179 600mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS986179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
35mg/mL	

Number of subjects in period 1	P1A 150mg	P1A 300mg	P1A 600mg
Started	14	12	12
Continuing to Combo Therapy	12	11	12
Crossing over to RCC combo therapy	0 ^[1]	0 ^[2]	0 ^[3]
Completed	1	2	4
Not completed	13	10	8
Disease progression	11	7	8
Study drug toxicity	1	1	-
Request to discontinue	-	-	-
Maximum clinical benefit	-	-	-
AE unrelated to study drug	1	1	-
No longer meets study criteria	-	-	-
Other reasons	-	-	-
Withdrew consent	-	-	-
Completed treatment as per protocol	-	1	-
Not completing monotherapy	-	-	-

Number of subjects in period 1	P1A 1200mg	P1A 1600mg	P1B Combo Therapy 150mg
Started	9	12	9
Continuing to Combo Therapy	7	10	0
Crossing over to RCC combo therapy	0 ^[4]	0 ^[5]	0
Completed	1	2	0
Not completed	8	10	9
Disease progression	5	7	7
Study drug toxicity	-	-	-
Request to discontinue	-	-	-
Maximum clinical benefit	1	-	-
AE unrelated to study drug	1	3	2
No longer meets study criteria	1	-	-
Other reasons	-	-	-
Withdrew consent	-	-	-
Completed treatment as per protocol	-	-	-
Not completing monotherapy	-	-	-

Number of subjects in period 1	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg	P1B BMS986-179 1600mg
Started	8	7	18
Continuing to Combo Therapy	0	0	0 ^[6]
Crossing over to RCC combo therapy	0	0	0 ^[7]
Completed	0	0	6
Not completed	8	7	12
Disease progression	7	6	11
Study drug toxicity	-	-	-
Request to discontinue	-	-	1
Maximum clinical benefit	-	-	-
AE unrelated to study drug	1	-	-
No longer meets study criteria	-	-	-
Other reasons	-	1	-
Withdrew consent	-	-	-
Completed treatment as per protocol	-	-	-
Not completing monotherapy	-	-	-

Number of subjects in period 1	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Started	19	31	15
Continuing to Combo Therapy	0 ^[8]	0 ^[9]	0 ^[10]
Crossing over to RCC combo therapy	0 ^[11]	0 ^[12]	0 ^[13]

Completed	2	11	1
Not completed	17	20	14
Disease progression	16	18	13
Study drug toxicity	-	2	1
Request to discontinue	-	-	-
Maximum clinical benefit	-	-	-
AE unrelated to study drug	-	-	-
No longer meets study criteria	-	-	-
Other reasons	-	-	-
Withdrew consent	1	-	-
Completed treatment as per protocol	-	-	-
Not completing monotherapy	-	-	-

Number of subjects in period 1	P2 Combo SCCHN	P2 RCC Monotherapy	P2 RCC Combo Therapy
Started	15	19	18
Continuing to Combo Therapy	0 ^[14]	0 ^[15]	0 ^[16]
Crossing over to RCC combo therapy	0 ^[17]	3 ^[18]	0 ^[19]
Completed	1	5	5
Not completed	14	14	13
Disease progression	10	12	12
Study drug toxicity	1	-	-
Request to discontinue	-	1	1
Maximum clinical benefit	-	-	-
AE unrelated to study drug	-	-	-
No longer meets study criteria	-	-	-
Other reasons	2	-	-
Withdrew consent	-	-	-
Completed treatment as per protocol	1	-	-
Not completing monotherapy	-	1	-

Number of subjects in period 1	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Started	14	2	1
Continuing to Combo Therapy	0	0 ^[20]	0
Crossing over to RCC combo therapy	0	0 ^[21]	0
Completed	0	2	0
Not completed	14	0	1
Disease progression	14	-	1
Study drug toxicity	-	-	-
Request to discontinue	-	-	-
Maximum clinical benefit	-	-	-

AE unrelated to study drug	-	-	-
No longer meets study criteria	-	-	-
Other reasons	-	-	-
Withdrew consent	-	-	-
Completed treatment as per protocol	-	-	-
Not completing monotherapy	-	-	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: No subjects in this milestone for this arm

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[18] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[19] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[20] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

[21] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subjects in this milestone for this arm

Baseline characteristics

Reporting groups

Reporting group title	P1A 150mg
Reporting group description: BMS-986179 150mg monotherapy leading into BMS-986179 150mg + Nivo 240 combo therapy	
Reporting group title	P1A 300mg
Reporting group description: BMS-986179 300mg monotherapy leading into BMS-986179 300mg + Nivo 240mg combo therapy	
Reporting group title	P1A 600mg
Reporting group description: BMS-986179 600mg monotherapy leading into BMS-986179 600mg + Nivo 240mg combo therapy	
Reporting group title	P1A 1200mg
Reporting group description: BMS-986179 1200mg monotherapy leading into BMS-986179 1200mg + Nivo 240mg combo therapy	
Reporting group title	P1A 1600mg
Reporting group description: BMS-986179 1600mg monotherapy leading into BMS-986179 1600mg + Nivo 240mg combo therapy	
Reporting group title	P1B Combo Therapy 150mg
Reporting group description: BMS-986179 150mg + Nivo 360mg	
Reporting group title	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg
Reporting group description: BMS-986179 1200mg + Nivo 360mg	
Reporting group title	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Reporting group description: BMS-986179 1200mg + Nivo 480mg	
Reporting group title	P1B BMS986-179 1600mg
Reporting group description: BMS-986179 1600mg SC	
Reporting group title	P2 Combo Pancreatic
Reporting group description: BMS-986179 1200mg Q2W + Nivo 240mg Q2W	
Reporting group title	P2 Combo Therapy NSCLC
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 Combo Melanoma
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 Combo SCCHN
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 RCC Monotherapy
Reporting group description: BMS-986179 600mg Q2W monotherapy	
Reporting group title	P2 RCC Combo Therapy
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W combo therapy	
Reporting group title	P2 Combo Prostate
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	

Reporting group title	P2 Combo Unassigned
Reporting group description: BMS-986179 1200mg Q2W + Nivo 240mg Q2W	
Reporting group title	P2 Monotherapy Unassigned
Reporting group description: BMS-986179 600mg Q2W	

Reporting group values	P1A 150mg	P1A 300mg	P1A 600mg
Number of subjects	14	12	12
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	7	9	10
>=65 years	7	3	2
Sex: Female, Male Units: Participants			
Female	8	5	2
Male	6	7	10
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	14	11	10
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	5	4	6
Unknown or Not Reported	9	7	6

Reporting group values	P1A 1200mg	P1A 1600mg	P1B Combo Therapy 150mg
Number of subjects	9	12	9
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	5	7	5
>=65 years	4	5	4
Sex: Female, Male Units: Participants			
Female	3	7	7
Male	6	5	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	1
White	8	12	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	4	5	4
Unknown or Not Reported	5	7	5

Reporting group values	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg	P1B BMS986-179 1600mg
Number of subjects	8	7	18
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	7	5	11
>=65 years	1	2	7
Sex: Female, Male			
Units: Participants			
Female	4	2	10
Male	4	5	8
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	7	5	14
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	7	11
Unknown or Not Reported	5	0	7

Reporting group values	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Number of subjects	19	31	15
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	14	14	8
>=65 years	5	17	7
Sex: Female, Male			
Units: Participants			
Female	8	10	9
Male	11	21	6

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	19	30	15
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	1	3
Unknown or Not Reported	8	30	12

Reporting group values	P2 Combo SCCHN	P2 RCC Monotherapy	P2 RCC Combo Therapy
Number of subjects	15	19	18
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	6	12	12
>=65 years	9	7	6
Sex: Female, Male			
Units: Participants			
Female	1	13	13
Male	14	6	5
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	
White	14	18	18
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	2	12	12
Unknown or Not Reported	12	7	6

Reporting group values	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Number of subjects	14	2	1
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	5	2	1
>=65 years	9	0	0

Sex: Female, Male			
Units: Participants			
Female	0	0	0
Male	14	2	1
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	13	1	1
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	2	0
Unknown or Not Reported	14	0	1

Reporting group values	Total		
Number of subjects	235		
Age Categorical			
Units: Participants			
<=18 years	0		
Between 18 and 65 years	140		
>=65 years	95		
Sex: Female, Male			
Units: Participants			
Female	102		
Male	133		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	8		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	5		
White	218		
More than one race	0		
Unknown or Not Reported	4		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2		
Not Hispanic or Latino	92		
Unknown or Not Reported	141		

Subject analysis sets

Subject analysis set title	P2 RCC Combo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W combo therapy

Subject analysis set title	P1A Combo Therapy 150mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 150mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 300mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 300mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 600mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 600mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 1200mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 1200mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 1600mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 1600mg + Nivo 240mg

Subject analysis set title	P2 Combo RCC Crossover
Subject analysis set type	Intention-to-treat

Subject analysis set description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg
Number of subjects	18	12	11
Age Categorical Units: Participants			
<=18 years	0		
Between 18 and 65 years	12		
>=65 years	6		
Sex: Female, Male Units: Participants			
Female	5		
Male	13		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	0		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	18		
More than one race	0		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0		

Not Hispanic or Latino	12		
Unknown or Not Reported	6		

Reporting group values	P1A Combo Therapy 600mg	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg
Number of subjects	12	7	10
Age Categorical Units: Participants			
<=18 years			
Between 18 and 65 years			
>=65 years			
Sex: Female, Male Units: Participants			
Female			
Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

Reporting group values	P2 Combo RCC Crossover		
Number of subjects	3		
Age Categorical Units: Participants			
<=18 years			
Between 18 and 65 years			
>=65 years			
Sex: Female, Male Units: Participants			
Female			
Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			

Unknown or Not Reported			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			

End points

End points reporting groups

Reporting group title	P1A 150mg
Reporting group description: BMS-986179 150mg monotherapy leading into BMS-986179 150mg + Nivo 240 combo therapy	
Reporting group title	P1A 300mg
Reporting group description: BMS-986179 300mg monotherapy leading into BMS-986179 300mg + Nivo 240mg combo therapy	
Reporting group title	P1A 600mg
Reporting group description: BMS-986179 600mg monotherapy leading into BMS-986179 600mg + Nivo 240mg combo therapy	
Reporting group title	P1A 1200mg
Reporting group description: BMS-986179 1200mg monotherapy leading into BMS-986179 1200mg + Nivo 240mg combo therapy	
Reporting group title	P1A 1600mg
Reporting group description: BMS-986179 1600mg monotherapy leading into BMS-986179 1600mg + Nivo 240mg combo therapy	
Reporting group title	P1B Combo Therapy 150mg
Reporting group description: BMS-986179 150mg + Nivo 360mg	
Reporting group title	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg
Reporting group description: BMS-986179 1200mg + Nivo 360mg	
Reporting group title	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Reporting group description: BMS-986179 1200mg + Nivo 480mg	
Reporting group title	P1B BMS986-179 1600mg
Reporting group description: BMS-986179 1600mg SC	
Reporting group title	P2 Combo Pancreatic
Reporting group description: BMS-986179 1200mg Q2W + Nivo 240mg Q2W	
Reporting group title	P2 Combo Therapy NSCLC
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 Combo Melanoma
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 Combo SCCHN
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W	
Reporting group title	P2 RCC Monotherapy
Reporting group description: BMS-986179 600mg Q2W monotherapy	
Reporting group title	P2 RCC Combo Therapy
Reporting group description: BMS-986179 600mg Q2W + Nivo 480mg Q4W combo therapy	
Reporting group title	P2 Combo Prostate

Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 Combo Unassigned
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Reporting group description:

BMS-986179 1200mg Q2W + Nivo 240mg Q2W

Reporting group title	P2 Monotherapy Unassigned
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Reporting group description:

BMS-986179 600mg Q2W

Subject analysis set title	P2 RCC Combo
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W combo therapy

Subject analysis set title	P1A Combo Therapy 150mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 150mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 300mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 300mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 600mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 600mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 1200mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 1200mg + Nivo 240mg

Subject analysis set title	P1A Combo Therapy 1600mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 1600mg + Nivo 240mg

Subject analysis set title	P2 Combo RCC Crossover
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Primary: Number of participants with drug related AEs, SAEs, AEs leading to discontinuation and deaths.

End point title	Number of participants with drug related AEs, SAEs, AEs leading to discontinuation and deaths. ^{[1][2]}
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End point description:

Number of participants with drug related adverse events (AE), drug related serious adverse events (SAE), drug related AEs Leading to discontinuation and drug related deaths

End point type	Primary
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End point timeframe:

From first dose to 100 days post last dose: Part 1 up to 25.1 months, Part 2 SC up to 17.5 months, RCC Mono up to 28.1 months, Part 2 up to 27.2 months.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No subjects analyzed for this arm

[2] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Participants				
Adverse Events	7	4	3	4
Serious Adverse Events	0	0	0	0
AEs Leading to Discontinuation	0	0	0	0
Deaths	0	0	0	0

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7
Units: Participants				
Adverse Events	5	5	1	2
Serious Adverse Events	0	0	0	0
AEs Leading to Discontinuation	0	0	0	0
Deaths	0	0	0	0

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Participants				
Adverse Events	4	11	21	7
Serious Adverse Events	0	0	1	1
AEs Leading to Discontinuation	0	0	2	1
Deaths	0	0	0	0

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Participants				
Adverse Events	12	8	1	0
Serious Adverse Events	1	0	0	0
AEs Leading to Discontinuation	1	0	0	0
Deaths	0	0	0	0

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	12	11	12
Units: Participants				
Adverse Events	15	7	7	6
Serious Adverse Events	1	2	0	1
AEs Leading to Discontinuation	0	2	0	0
Deaths	0	0	0	0

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	3	
Units: Participants				
Adverse Events	5	7	3	
Serious Adverse Events	0	1	0	
AEs Leading to Discontinuation	0	0	0	
Deaths	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with a best overall response (BOR) at week 24

End point title	Number of participants with a best overall response (BOR) at week 24 ^[3]
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End point description:

Best overall response (BOR) is defined as the best response designation over the study as a whole, recorded between the dates of first dose until the last tumor assessment prior to subsequent therapy. CR or PR determinations included in the BOR assessment must be confirmed by a second scan performed no less than 4 weeks after the criteria for response are first met.

End point type	Secondary
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End point timeframe:

from initial treatment to week 24

Notes:

[3] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	0	0	0

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	0	0	0

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	1	1	0

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Participants				
Complete Response	1	0	0	0
Partial Response	1	0	0	0

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	12	11	12
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	1	1	2

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	3	
Units: Participants				
Complete Response	0	0	0	
Partial Response	1	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with an objective response rate (ORR) at week 24

End point title	Percentage of participants with an objective response rate (ORR) at week 24 ^[4]
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End point description:

ORR is defined as the percentage of all treated participants whose BOR is either a CR or PR.

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

from initial treatment to week 24

Notes:

[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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 84.2)	0 (0.0 to 97.5)	0 (-99999 to 99999)	0 (-99999 to 99999)

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 84.2)	0 (0.0 to 33.6)	0 (0.0 to 36.9)	0 (0.0 to 41.0)

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 18.5)	5.3 (0.1 to 26.0)	3.2 (0.1 to 16.7)	0 (0.0 to 21.8)

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Percentage of Participants				
number (confidence interval 95%)	13.3 (1.7 to 40.5)	0 (0.0 to 23.2)	0 (0.0 to 84.2)	0 (0.0 to 97.5)

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	12	11	12
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 18.5)	8.3 (0.2 to 38.5)	9.1 (0.2 to 41.3)	16.7 (2.1 to 48.4)

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	3	
Units: Percentage of Participants				
number (confidence interval 95%)	14.3 (0.4 to 57.9)	10.0 (0.3 to 44.5)	0 (0.0 to 70.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival rate (PFSR) at week 24

End point title	Progression free survival rate (PFSR) at week 24 ^[5]
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End point description:

PFSR at 24 weeks is defined as the percentage of treated participants remaining progression free and surviving at 24 weeks.

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

from initial treatment to week 24

Notes:

[5] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Percentage				
number (confidence interval 95%)	7.1 (1.3 to 98.7)	8.3 (2.5 to 100.0)	0 (-99999 to 99999)	11.1 (1.3 to 98.7)

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7
Units: Percentage				
number (confidence interval 95%)	16.7 (15.8 to 100.0)	88.9 (51.8 to 99.7)	87.5 (47.3 to 99.7)	100.00 (59.0 to 100.0)

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Percentage				
number (confidence interval 95%)	88.9 (65.3 to 98.6)	94.7 (74.0 to 99.9)	71.0 (52.0 to 85.8)	86.7 (59.5 to 98.3)

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Percentage				
number (confidence interval 95%)	80.0 (51.9 to 95.7)	71.4 (41.9 to 91.6)	50.0 (1.3 to 98.7)	100.0 (2.5 to 100.0)

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	12	11	12
Units: Percentage				
number (confidence interval 95%)	72.2 (46.5 to 90.3)	83.3 (51.6 to 97.9)	72.7 (39.0 to 94.0)	75.0 (42.8 to 94.5)

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	3	
Units: Percentage				
number (confidence interval 95%)	57.1 (18.4 to 90.1)	70.0 (34.8 to 93.3)	66.7 (9.4 to 99.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Median duration of response (DOR)

End point title	Median duration of response (DOR) ^[6]
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End point description:

DOR (computed for all treated subjects with a BOR of CR or PR) is defined as the time between the date of first response and the date of disease progression or death, whichever occurs first.

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

from first measure response approximately up to 25 months

Notes:

[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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Months				
median (full range (min-max))	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7
Units: Months				
median (full range (min-max))	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Months				
median (full range (min-max))	99999 (-99999 to 99999)	3.90 (3.9 to 3.9)	3.80 (3.8 to 3.8)	99999 (-99999 to 99999)

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Months				
median (full range (min-max))	6.70 (3.8 to 9.6)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	12	11	12
Units: Months				
median (full range (min-max))	99999 (-99999 to 99999)	17.40 (17.4 to 17.4)	5.70 (5.7 to 5.7)	9.30 (7.2 to 11.4)

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	3	

Units: Months				
median (full range (min-max))	2.10 (2.1 to 2.1)	24.40 (24.4 to 24.4)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax

End point title	Cmax ^[7]
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End point description:

Cmax is defined as maximum plasma concentration of the drug

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

Part 1A Cycle 0 = 14 days Cycle 1 = 28 days Part 1B and Part 2 Q2W regimen Cycle 0 = 14 days Cycle 1 = 28 days Cycle 2 = 28 days Part 1B and 2 Q4W Regimen Cycle 1= 28 days Cycle 2 = 28 days Cycle 4 = 28 days

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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	0 ^[8]	9
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	30.6524 (± 66)	94.9210 (± 99999)	()	218.0423 (± 8)
Cycle 1 Day 1	99999 (± 99999)	9999999999 (± 99999)	()	99999 (± 99999)
Cycle 1 Day 22	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
Cycle 2 Day 1	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
cycle 4 Day 15	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)

Notes:

[8] - No subjects analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[9]	0 ^[10]	0 ^[11]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				

Cycle 0 Day 1	499.5178 (\pm 10)	()	()	()
Cycle 1 Day 1	99999 (\pm 99999)	()	()	()
Cycle 1 Day 22	99999 (\pm 99999)	()	()	()
Cycle 2 Day 1	99999 (\pm 99999)	()	()	()
cycle 4 Day 15	99999 (\pm 99999)	()	()	()

Notes:

[9] - No subjects analyzed

[10] - No subjects analyzed

[11] - No subjects analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0 ^[12]	0 ^[13]	0 ^[14]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	99999 (\pm 99999)	()	()	()
Cycle 1 Day 1	93.7415 (\pm 33)	()	()	()
Cycle 1 Day 22	99999 (\pm 99999)	()	()	()
Cycle 2 Day 1	563.4487 (\pm 27)	()	()	()
cycle 4 Day 15	99999 (\pm 99999)	()	()	()

Notes:

[12] - No subjects analyzed

[13] - No subjects analyzed

[14] - No subjects analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[15]	0 ^[16]	0 ^[17]	0 ^[18]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	()	()	()
Cycle 1 Day 1	()	()	()	()
Cycle 1 Day 22	()	()	()	()
Cycle 2 Day 1	()	()	()	()
cycle 4 Day 15	()	()	()	()

Notes:

[15] - No subjects analyzed

[16] - No subjects analyzed

[17] - No subjects analyzed

[18] - No subjects analyzed

End point values	P2 RCC Combo	P1A Combo Therapy	P1A Combo Therapy	P1A Combo Therapy
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		150mg	300mg	600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[19]	12	11	12
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	28.8892 (± 25)	64.3400 (± 55)	141.3732 (± 26)
Cycle 1 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 1 Day 22	()	51.3637 (± 38)	99.3564 (± 47)	289.8829 (± 27)
Cycle 2 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
cycle 4 Day 15	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[19] - No subjects analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[20]	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	315.6963 (± 16)	453.5664 (± 27)	()	
Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	()	
Cycle 1 Day 22	722.2768 (± 32)	865.8497 (± 22)	()	
Cycle 2 Day 1	99999 (± 99999)	99999 (± 99999)	()	
cycle 4 Day 15	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[20] - No subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax

End point title Tmax^[21]

End point description:

Tmax is defined is the time to maximum plasma concentration

Here "99999 and -99999" means not available

End point type Secondary

End point timeframe:

Part 1A Cycle 0 = 14 days Cycle 1 = 28 days Part 1B and Part 2 Q2W regimen Cycle 0 = 14 days Cycle 1 = 28 days Cycle 2 = 28 days Part 1B and 2 Q4W Regimen Cycle 1= 28 days Cycle 2 = 28 days Cycle 4 = 28 days

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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	0 ^[22]	9
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	2.409 (0.800 to 4.017)	0.933 (0.933 to 0.933)	(to)	2.992 (1.983 to 4.00)
Cycle 1 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)
Cycle 1 Day 22	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)
Cycle 2 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)
cycle 4 Day 15	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)

Notes:

[22] - no subjects analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[23]	0 ^[24]	0 ^[25]
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	2.700 (2.400 to 3.00)	(to)	(to)	(to)
Cycle 1 Day 1	99999 (99999 to 99999)	(to)	(to)	(to)
Cycle 1 Day 22	99999 (99999 to 99999)	(to)	(to)	(to)
Cycle 2 Day 1	99999 (99999 to 99999)	(to)	(to)	(to)
cycle 4 Day 15	99999 (99999 to 99999)	(to)	(to)	(to)

Notes:

[23] - no subjects analyzed

[24] - no subjects analyzed

[25] - no subjects analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0 ^[26]	0 ^[27]	0 ^[28]
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	99999 (99999 to 99999)	(to)	(to)	(to)

Cycle 1 Day 1	96.200 (48.017 to 168.267)	(to)	(to)	(to)
Cycle 1 Day 22	99999 (99999 to 99999)	(to)	(to)	(to)
Cycle 2 Day 1	4.000 (1.967 to 24.667)	(to)	(to)	(to)
cycle 4 Day 15	99999 (99999 to 99999)	(to)	(to)	(to)

Notes:

[26] - no subjects analyzed

[27] - no subjects analyzed

[28] - no subjects analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[29]	0 ^[30]	0 ^[31]	0 ^[32]
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	(to)	(to)	(to)	(to)
Cycle 1 Day 1	(to)	(to)	(to)	(to)
Cycle 1 Day 22	(to)	(to)	(to)	(to)
Cycle 2 Day 1	(to)	(to)	(to)	(to)
cycle 4 Day 15	(to)	(to)	(to)	(to)

Notes:

[29] - no subjects analyzed

[30] - no subjects analyzed

[31] - no subjects analyzed

[32] - no subjects analyzed

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[33]	12	11	12
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	(to)	1.00 (0.967 to 8.250)	2.942 (0.967 to 8.00)	1.109 (0.867 to 24.050)
Cycle 1 Day 1	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Cycle 1 Day 22	(to)	4.000 (0.967 to 9.050)	7.767 (4.067 to 95.950)	4.000 (0.967 to 7.933)
Cycle 2 Day 1	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
cycle 4 Day 15	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Notes:

[33] - no subjects analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[34]	
Units: hours				
median (full range (min-max))				
Cycle 0 Day 1	4.000 (1.967 to 8.000)	3.692 (1.783 to 24.117)	(to)	
Cycle 1 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
Cycle 1 Day 22	8.000 (2.100 to 10.050)	4.000 (1.983 to 8.000)	(to)	
Cycle 2 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
cycle 4 Day 15	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[34] - no subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-T)

End point title	AUC (0-T) ^[35]
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End point description:

Area under the plasma concentration time-curve. AUC from time 0 to the last time of quantifiable concentration

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

Part 1A Cycle 0 = 14 days Cycle 1 = 28 days Part 1B and Part 2 Q2W regimen Cycle 0 = 14 days Cycle 1 = 28 days Cycle 2 = 28 days Part 1B and 2 Q4W Regimen Cycle 1= 28 days Cycle 2 = 28 days Cycle 4 = 28 days

Notes:

[35] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	0 ^[36]	9
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	1414.4834 (± 76)	2565.0489 (± 99999)	()	9362.9155 (± 39)
Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
Cycle 1 Day 22	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
Cycle 2 Day 1	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
cycle 4 Day 15	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)

Notes:

[36] - no subjects analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[37]	0 ^[38]	0 ^[39]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	30716.0037 (± 47)	()	()	()
Cycle 1 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	99999 (± 99999)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[37] - no subjects analyzed

[38] - no subjects analyzed

[39] - no subjects analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0 ^[40]	0 ^[41]	0 ^[42]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 1	41672.2787 (± 35)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	84384.9379 (± 36)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[40] - no subjects analyzed

[41] - no subjects analyzed

[42] - no subjects analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[43]	0 ^[44]	0 ^[45]	0 ^[46]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				

Cycle 0 Day 1	()	()	()	()
Cycle 1 Day 1	()	()	()	()
Cycle 1 Day 22	()	()	()	()
Cycle 2 Day 1	()	()	()	()
cycle 4 Day 15	()	()	()	()

Notes:

[43] - no subjects analyzed

[44] - no subjects analyzed

[45] - no subjects analyzed

[46] - no subjects analyzed

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[47]	12	11	12
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	1225.3679 (± 36)	3418.8393 (± 62)	9139.4853 (± 30)
Cycle 1 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 1 Day 22	()	3932.5889 (± 44)	9622.5237 (± 58)	27616.4807 (± 40)
Cycle 2 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
cycle 4 Day 15	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[47] - no subjects analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[48]	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	23533.0706 (± 9)	31057.8588 (± 26)	()	
Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	()	
Cycle 1 Day 22	74405.3428 (± 25)	92340.2959 (± 21)	()	
Cycle 2 Day 1	99999 (± 99999)	99999 (± 99999)	()	
cycle 4 Day 15	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[48] - no subjects analyzed

Statistical analyses

Secondary: AUC (Tau)

End point title	AUC (Tau) ^[49]
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End point description:

Area under the plasma concentration time-curve. AUC over the dosing interval.

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

Part 1A Cycle 0 = 14 days Cycle 1 = 28 days Part 1B and Part 2 Q2W regimen Cycle 0 = 14 days Cycle 1 = 28 days Cycle 2 = 28 days Part 1B and 2 Q4W Regimen Cycle 1 = 28 days Cycle 2 = 28 days Cycle 4 = 28 days

Notes:

[49] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	0 ^[50]	0 ^[51]	0 ^[52]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	1417.4834 (± 76)	()	()	()
Cycle 1 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	99999 (± 99999)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[50] - No subjects analyzed

[51] - No subjects analyzed

[52] - No subjects analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[53]	0 ^[54]	0 ^[55]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	34198.6293 (± 33)	()	()	()
Cycle 1 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()

Cycle 2 Day 1	99999 (± 99999)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[53] - No subjects analyzed

[54] - No subjects analyzed

[55] - No subjects analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0 ^[56]	0 ^[57]	0 ^[58]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 1	40833.1977 (± 36)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	92770.2634 (± 30)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[56] - No subjects analyzed

[57] - No subjects analyzed

[58] - No subjects analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[59]	0 ^[60]	0 ^[61]	0 ^[62]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	()	()	()
Cycle 1 Day 1	()	()	()	()
Cycle 1 Day 22	()	()	()	()
Cycle 2 Day 1	()	()	()	()
cycle 4 Day 15	()	()	()	()

Notes:

[59] - No subjects analyzed

[60] - No subjects analyzed

[61] - No subjects analyzed

[62] - No subjects analyzed

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[63]	12	11	12
Units: h*ug/mL				
geometric mean (geometric coefficient				

of variation)				
Cycle 0 Day 1	()	1307.7132 (± 33)	3546.1659 (± 59)	9139.4853 (± 30)
Cycle 1 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 1 Day 22	()	3975.0900 (± 46)	12326.2351 (± 44)	30044.3813 (± 35)
Cycle 2 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
cycle 4 Day 15	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[63] - No subjects analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[64]	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	23533.0706 (± 9)	34970.3626 (± 12)	()	
Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	()	
Cycle 1 Day 22	74405.3428 (± 25)	92340.2959 (± 21)	()	
Cycle 2 Day 1	99999 (± 99999)	99999 (± 99999)	()	
cycle 4 Day 15	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[64] - No subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Ctau

End point title	Ctau ^[65]
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End point description:

Ctau is defined as the concentration of study drug at the end of the dosing interval.

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

Part 1A Cycle 0 = 14 days Cycle 1 = 28 days Part 1B and Part 2 Q2W regimen Cycle 0 = 14 days Cycle 1 = 28 days Cycle 2 = 28 days Part 1B and 2 Q4W Regimen Cycle 1 = 28 days Cycle 2 = 28 days Cycle 4 = 28 days

Notes:

[65] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	0 ^[66]	0 ^[67]	0 ^[68]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	1.9173 (± 99)	()	()	()
Cycle 1 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	99999 (± 99999)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[66] - No Subjects Analyzed

[67] - No Subjects Analyzed

[68] - No Subjects Analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[69]	0 ^[70]	0 ^[71]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	82.2225 (± 82)	()	()	()
Cycle 1 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	99999 (± 99999)	()	()	()
cycle 4 Day 15	99999 (± 99999)	()	()	()

Notes:

[69] - No Subjects Analyzed

[70] - No Subjects Analyzed

[71] - No Subjects Analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0 ^[72]	0 ^[73]	0 ^[74]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	99999 (± 99999)	()	()	()
Cycle 1 Day 1	30.0008 (± 51)	()	()	()
Cycle 1 Day 22	99999 (± 99999)	()	()	()
Cycle 2 Day 1	52.9049 (± 71)	()	()	()

cycle 4 Day 15	99999 (± 99999)	()	()	()
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Notes:

[72] - No Subjects Analyzed

[73] - No Subjects Analyzed

[74] - No Subjects Analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[75]	0 ^[76]	0 ^[77]	0 ^[78]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	()	()	()
Cycle 1 Day 1	()	()	()	()
Cycle 1 Day 22	()	()	()	()
Cycle 2 Day 1	()	()	()	()
cycle 4 Day 15	()	()	()	()

Notes:

[75] - No Subjects Analyzed

[76] - No Subjects Analyzed

[77] - No Subjects Analyzed

[78] - No Subjects Analyzed

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[79]	12	11	12
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	()	0.8999 (± 74)	5.4691 (± 59)	25.9755 (± 32)
Cycle 1 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 1 Day 22	()	14.5545 (± 54)	51.0567 (± 44)	126.4960 (± 37)
Cycle 2 Day 1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
cycle 4 Day 15	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[79] - No Subjects Analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[80]	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 0 Day 1	74.8859 (± 30)	99.0307 (± 14)	()	

Cycle 1 Day 1	99999 (\pm 99999)	99999 (\pm 99999)	()	
Cycle 1 Day 22	366.8165 (\pm 21)	466.5231 (\pm 32)	()	
Cycle 2 Day 1	99999 (\pm 99999)	99999 (\pm 99999)	()	
cycle 4 Day 15	99999 (\pm 99999)	99999 (\pm 99999)	()	

Notes:

[80] - No Subjects Analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CD73 assays

End point title	Mean change from baseline in CD73 assays ^[81]
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End point description:

Mean change from baseline in CD73 assays at the end of Part 1A treatment period

Assays Measured:

EHC CD73 H-score

IHC CD73 Cytoplasm H-Score

IHC CDS73 Membrane H-Score

Here "99999 and -99999" means not available

End point type	Secondary
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End point timeframe:

approximately up to 95 weeks

Notes:

[81] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	0 ^[82]	9
Units: mean change from baseline arithmetic mean (standard error)				
EHC CD73 H-Score	-33.790 (\pm 25.5200)	-103.700 (\pm 90.3400)	()	-204.710 (\pm 99999)
IHC CD73 Cytoplasm H-Score	1.5 (\pm 2.60)	-0.3 (\pm 32.04)	()	17.0 (\pm 99999)
IHC CD73 Membrane H-Score	7.3 (\pm 6.77)	8.7 (\pm 30.33)	()	88.0 (\pm 99999)

Notes:

[82] - No subjects analyzed

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	0 ^[83]	0 ^[84]	0 ^[85]
Units: mean change from baseline arithmetic mean (standard error)				

EHC CD73 H-Score	-3.220 (\pm 51.7800)	()	()	()
IHC CD73 Cytoplasm H-Score	0.0 (\pm 0.00)	()	()	()
IHC CD73 Membrane H-Score	0.00 (\pm 0.00)	()	()	()

Notes:

[83] - No subjects analyzed

[84] - No subjects analyzed

[85] - No subjects analyzed

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[86]	0 ^[87]	0 ^[88]	0 ^[89]
Units: mean change from baseline				
arithmetic mean (standard error)				
EHC CD73 H-Score	()	()	()	()
IHC CD73 Cytoplasm H-Score	()	()	()	()
IHC CD73 Membrane H-Score	()	()	()	()

Notes:

[86] - No subjects analyzed

[87] - No subjects analyzed

[88] - No subjects analyzed

[89] - No subjects analyzed

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[90]	0 ^[91]	0 ^[92]	0 ^[93]
Units: mean change from baseline				
arithmetic mean (standard error)				
EHC CD73 H-Score	()	()	()	()
IHC CD73 Cytoplasm H-Score	()	()	()	()
IHC CD73 Membrane H-Score	()	()	()	()

Notes:

[90] - No subjects analyzed

[91] - No subjects analyzed

[92] - No subjects analyzed

[93] - No subjects analyzed

End point values	P2 RCC Combo	P1A Combo Therapy 150mg	P1A Combo Therapy 300mg	P1A Combo Therapy 600mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[94]	12	11	0 ^[95]
Units: mean change from baseline				
arithmetic mean (standard error)				
EHC CD73 H-Score	()	-33.790 (\pm 28.5200)	-103.700 (\pm 90.3400)	()
IHC CD73 Cytoplasm H-Score	()	1.5 (\pm 2.60)	-0.3 (\pm 32.04)	()
IHC CD73 Membrane H-Score	()	7.3 (\pm 6.77)	8.7 (\pm 30.33)	()

Notes:

[94] - No subjects analyzed

[95] - No subjects analyzed

End point values	P1A Combo Therapy 1200mg	P1A Combo Therapy 1600mg	P2 Combo RCC Crossover	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	10	0 ^[96]	
Units: mean change from baseline				
arithmetic mean (standard error)				
EHC CD73 H-Score	-204.710 (± 99999)	-3.220 (± 51.7800)	()	
IHC CD73 Cytoplasm H-Score	17.0 (± 99999)	0.0 (± 0.00)	()	
IHC CD73 Membrane H-Score	88.0 (± 99999)	0.0 (± 0.00)	()	

Notes:

[96] - No subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with a positive anti-drug antibody (ADA) test.

End point title	Number of participants with a positive anti-drug antibody (ADA) test. ^[97]
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End point description:

A participant with at least one ADA-positive sample relative to baseline at any time after initiation of treatment with BMS-986179 and nivolumab.

End point type	Secondary
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End point timeframe:

From first dose to last dose: Part 1: up to 95 weeks, Part 2 SC: up to 62 weeks, RCC Mono: up to 108 weeks, Part 2: up to 104 weeks

Notes:

[97] - 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: No subjects analyzed for this arm

End point values	P1A 150mg	P1A 300mg	P1A 600mg	P1A 1200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	12	9
Units: Participants				
BMS-986179 ADA+	5	4	8	3
Nivolumab ADA+	0	1	0	0

End point values	P1A 1600mg	P1B Combo Therapy 150mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 360mg	P1B Combo Therapy BMS-986179 1200mg + Nivo 480mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	8	7

Units: Participants				
BMS-986179 ADA+	2	5	6	5
Nivolumab ADA+	0	1	1	0

End point values	P1B BMS986-179 1600mg	P2 Combo Pancreatic	P2 Combo Therapy NSCLC	P2 Combo Melanoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	31	15
Units: Participants				
BMS-986179 ADA+	11	9	22	9
Nivolumab ADA+	0	2	0	0

End point values	P2 Combo SCCHN	P2 Combo Prostate	P2 Combo Unassigned	P2 Monotherapy Unassigned
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	2	1
Units: Participants				
BMS-986179 ADA+	6	8	1	0
Nivolumab ADA+	0	0	0	0

End point values	P2 RCC Combo	P2 Combo RCC Crossover		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	3		
Units: Participants				
BMS-986179 ADA+	14	2		
Nivolumab ADA+	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part 1 up to 25.1 months, Part 2 SC up to 17.5 months, RCC Mono up to 28.1 months, Part 2 up to 27.2 months.

All-cause mortality will be measured from randomization to study completion: approximately up to 5 years and 4 months

Adverse event reporting additional description:

Serious adverse events and other adverse events will be measured from first dose to 100 days post last dose:

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	P1A BMS1200
Reporting group description: BMS-986179 1200mg monotherapy	
Reporting group title	P1A BMS150
Reporting group description: BMS-986179 150mg monotherapy	
Reporting group title	P1A BMS300
Reporting group description: BMS-986179 300mg monotherapy	
Reporting group title	P1A BMS600
Reporting group description: BMS-986179 600mg monotherapy	
Reporting group title	P1A BMS600+NIV240
Reporting group description: BMS-986179 600mg + Nivo 240mg	
Reporting group title	P1A BMS300+NIV240
Reporting group description: BMS-986179 300mg + Nivo 240mg	
Reporting group title	P1A BMS150+NIV240
Reporting group description: BMS-986179 150mg + Nivo 240mg	
Reporting group title	P1A ALL MONO
Reporting group description: P1A all treated participants in monotherapy	
Reporting group title	P1A BMS1200+NIV240
Reporting group description: BMS-986179 1200mg + Nivo 240mg	
Reporting group title	P1A BMS1600
Reporting group description: BMS-986179 1600mg monotherapy	
Reporting group title	P1B BMS1200+NIV360
Reporting group description: BMS-986179 1200mg + Nivo360mg	
Reporting group title	P1B BMS150+NIV360

Reporting group description:

BMS-986179 150mg + Nivo 360mg

Reporting group title	P1A ALL COMBO
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Reporting group description:

P1A all treated participants in combo therapy

Reporting group title	P1A BMS1600+NIV240
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Reporting group description:

BMS-986179 1600mg + Nivo 240mg

Reporting group title	P1B BMS1200+NIV480
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Reporting group description:

BMS-986179 1200mg + Nivo 480mg

Reporting group title	P1B BMS1600SC
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Reporting group description:

BMS-986179 1600mg SC

Reporting group title	P1B ALL COMBO
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Reporting group description:

All treated participants in P1B combo therapy period

Reporting group title	P2 PANCREATIC COMBO
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Reporting group description:

BMS-986179 1200mg Q2W + Nivo 240mg Q2W

Reporting group title	P2 NSCLC COMBO
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 MELANOMA COMBO
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 2 SCCHN COMBO
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 RCC COMBO
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 RCC MONO
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Reporting group description:

BMS-986179 600mg Q2W Monotherapy

Reporting group title	P2 RCC CROSSOVER
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 PROSTATE COMBO
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Reporting group description:

BMS-986179 600mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 NOT ASSIGNED MONO
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Reporting group description:

BMS-986179 600mg Q2W

Reporting group title	P2 NOT ASSIGNED COMBO
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Reporting group description:

BMS-986179 1200mg Q2W + Nivo 480mg Q4W

Reporting group title	P2 ALL COMBO
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Reporting group description:

All Treated participants in the P2 treatment period

Reporting group title	ALL COMBO (P1A+P1B+P2)
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Serious adverse events	P1A BMS1200	P1A BMS150	P1A BMS300
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)	3 / 14 (21.43%)	4 / 12 (33.33%)
number of deaths (all causes)	2	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
General physical health deterioration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Adjustment disorder			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (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

Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Carotid artery dissection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (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
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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	1 / 9 (11.11%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Back pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (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 infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 device infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P1A BMS600	P1A BMS600+NIV240	P1A BMS300+NIV240
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	9 / 12 (75.00%)	6 / 11 (54.55%)
number of deaths (all causes)	0	11	11
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	4 / 12 (33.33%)	4 / 11 (36.36%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Adjustment disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Carotid artery dissection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Obstruction gastric			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
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	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 failure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 11 (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
Bone pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 device infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
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	P1A BMS150+NIV240	P1A ALL MONO	P1A BMS1200+NIV240
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)	13 / 59 (22.03%)	3 / 7 (42.86%)
number of deaths (all causes)	9	7	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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	1 / 12 (8.33%)	4 / 59 (6.78%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			

General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	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
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	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
Delirium			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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	1 / 12 (8.33%)	0 / 59 (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
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	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
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Carotid artery dissection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Haemolysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 ischaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	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
Subileus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	3 / 59 (5.08%)	0 / 7 (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
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (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
Bone pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Spinal cord infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 device infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
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 / 12 (0.00%)	1 / 59 (1.69%)	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

Serious adverse events	P1A BMS1600	P1B BMS1200+NIV360	P1B BMS150+NIV360
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)	7 / 8 (87.50%)	7 / 9 (77.78%)
number of deaths (all causes)	2	8	9
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	2 / 12 (16.67%)	4 / 8 (50.00%)	3 / 9 (33.33%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid artery dissection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (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
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 9 (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
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 9 (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
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P1A ALL COMBO	P1A BMS1600+NIV240	P1B BMS1200+NIV480
Total subjects affected by serious adverse events			
subjects affected / exposed	28 / 52 (53.85%)	5 / 10 (50.00%)	4 / 7 (57.14%)
number of deaths (all causes)	45	8	5
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Malignant neoplasm progression			
subjects affected / exposed	13 / 52 (25.00%)	2 / 10 (20.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 13	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	1 / 52 (1.92%)	0 / 10 (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
Tumour pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			

General physical health deterioration			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (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
Performance status decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	1 / 52 (1.92%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (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
Haemoptysis			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (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
Pharyngeal necrosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Adjustment disorder			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Transaminases increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Weight decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Pericardial effusion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Carotid artery dissection			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Sciatica			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (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
Ascites			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (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
Colitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (1.92%)	0 / 10 (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
Intestinal ischaemia			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	2 / 52 (3.85%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (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
Nausea			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Pancreatitis			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 obstruction			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Subileus			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Vomiting			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (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
Immune-mediated hepatitis			

subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Hydronephrosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 failure			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (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
Bone pain			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (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
Bacteraemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (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
Spinal cord infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 device infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
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	P1B BMS1600SC	P1B ALL COMBO	P2 PANCREATIC COMBO
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 18 (61.11%)	18 / 24 (75.00%)	8 / 19 (42.11%)
number of deaths (all causes)	18	22	14
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 18 (0.00%)	2 / 24 (8.33%)	0 / 19 (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
Malignant neoplasm progression			
subjects affected / exposed	3 / 18 (16.67%)	9 / 24 (37.50%)	8 / 19 (42.11%)
occurrences causally related to treatment / all	0 / 3	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			

General physical health deterioration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Oedema peripheral			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Performance status decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Adjustment disorder			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Product issues			
Device malfunction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Weight decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Carotid artery dissection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Haemolysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Ascites			
subjects affected / exposed	0 / 18 (0.00%)	2 / 24 (8.33%)	0 / 19 (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
Colitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Diarrhoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Ileus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ischaemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Nausea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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 obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Immune-mediated hepatitis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Pericarditis infective			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 device infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (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
Hypercalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (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
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	P2 NSCLC COMBO	P2 MELANOMA COMBO	P2 2 SCCHN COMBO
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 31 (45.16%)	8 / 15 (53.33%)	11 / 15 (73.33%)
number of deaths (all causes)	23	14	13
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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	4 / 31 (12.90%)	6 / 15 (40.00%)	5 / 15 (33.33%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Neoplasm progression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

General physical health deterioration			
subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (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
Performance status decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (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
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Nervous system disorders			
Carotid artery dissection			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Hemiparesis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 ischaemia			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 chest pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Perinephric abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (3.23%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 infection			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (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
Tooth abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (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
Vascular device infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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	P2 RCC COMBO	P2 RCC MONO	P2 RCC CROSSOVER
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 18 (61.11%)	5 / 19 (26.32%)	1 / 3 (33.33%)
number of deaths (all causes)	9	8	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	2 / 19 (10.53%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Neoplasm malignant			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Neoplasm progression			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Tumour associated fever			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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			
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			

General physical health deterioration			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Oedema peripheral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Performance status decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	0 / 19 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Pharyngeal necrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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			
Adjustment disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Delirium			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Product issues			
Device malfunction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Transaminases increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Weight decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
Femoral neck fracture			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Pelvic fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (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
Myocardial infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Pericardial effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
Carotid artery dissection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	0 / 19 (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
Neuropathy peripheral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	0 / 19 (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
Syncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Haemolysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Diarrhoea			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 ischaemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Subileus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Hepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Immune-mediated hepatitis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
Back pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
Abdominal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Bacteraemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (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
Biliary tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Infusion site infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Pericarditis infective			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Perinephric abscess			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 aspiration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	0 / 19 (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
Spinal cord infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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
Tooth abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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	1 / 18 (5.56%)	0 / 19 (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
Urosepsis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 device infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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			
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 19 (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
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (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
Hyponatraemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (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

Serious adverse events	P2 PROSTATE COMBO	P2 NOT ASSIGNED MONO	P2 NOT ASSIGNED COMBO
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 14 (28.57%)	0 / 1 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	13	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (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
Neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (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
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			

General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Dyspnoea			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal necrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Adjustment disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (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
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Carotid artery dissection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 ischaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (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
Immune-mediated hepatitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (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
Renal failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis infective			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 device infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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	P2 ALL COMBO	ALL COMBO (P1A+P1B+P2)	
Total subjects affected by serious adverse events			
subjects affected / exposed	57 / 117 (48.72%)	103 / 193 (53.37%)	
number of deaths (all causes)	88	155	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	27 / 117 (23.08%)	49 / 193 (25.39%)	
occurrences causally related to treatment / all	0 / 27	0 / 49	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm progression			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
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	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haemorrhage			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

General physical health deterioration			
subjects affected / exposed	4 / 117 (3.42%)	4 / 193 (2.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Performance status decreased			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	6 / 117 (5.13%)	8 / 193 (4.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal necrosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery dissection			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolysis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (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 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			

subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 117 (2.56%)	6 / 193 (3.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion site infection			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis infective			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephric abscess			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (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	3 / 117 (2.56%)	4 / 193 (2.07%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord infection			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	P1A BMS1200	P1A BMS150	P1A BMS300
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 9 (66.67%)	11 / 14 (78.57%)	8 / 12 (66.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 14 (7.14%) 1	0 / 12 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Inferior vena cava stenosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Lymphoedema			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 9 (11.11%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Feeling cold			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Infusion site joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Xerosis			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testis discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ammonia increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Red blood cells urine positive subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Transaminases increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Tri-iodothyronine free decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Troponin I increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Fall			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Post procedural pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural site reaction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinoatrial block			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Amnesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 9 (22.22%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Tremor subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	1 / 14 (7.14%) 1	3 / 12 (25.00%) 3
Eosinophilia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Hyperleukocytosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Splenic vein thrombosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Middle ear effusion subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Middle ear inflammation			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eye disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Eye pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	2	0	2
Abdominal pain lower			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Dental caries			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	4 / 12 (33.33%)
occurrences (all)	0	1	5
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	4 / 12 (33.33%)
occurrences (all)	0	0	6
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Lichenoid keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain of skin			

subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Skin induration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vitiligo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 9 (22.22%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clubbing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Sarcopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Sepsis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Dehydration			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Folate deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypomagnesaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P1A BMS600	P1A BMS600+NIV240	P1A BMS300+NIV240
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	12 / 12 (100.00%)	11 / 11 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Neoplasm malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Inferior vena cava stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Device related thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Facial pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 12 (0.00%)	4 / 12 (33.33%)	4 / 11 (36.36%)
occurrences (all)	0	4	5
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	1 / 11 (9.09%)
occurrences (all)	1	2	2
Infusion site joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	5 / 11 (45.45%)
occurrences (all)	0	3	5
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Xerosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Testis discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	1 / 11 (9.09%)
occurrences (all)	1	5	1
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	3 / 11 (27.27%)
occurrences (all)	1	2	3
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	2 / 11 (18.18%)
occurrences (all)	0	3	2
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

Sleep disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Product issues Device dislocation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Ammonia increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Amylase decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	2 / 12 (16.67%) 2	1 / 11 (9.09%) 3
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Blood alkaline phosphatase decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 2	0 / 11 (0.00%) 0

Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	0 / 11 (0.00%)
occurrences (all)	0	4	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 11 (9.09%)
occurrences (all)	0	3	2
Blood glucose decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0

Blood triglycerides abnormal subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Glycosylated haemoglobin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Heart rate decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Lipase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 11 (9.09%)
occurrences (all)	0	5	4
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0

Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	1 / 11 (9.09%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 2	0 / 11 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 3	0 / 11 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Incision site pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Post procedural pruritus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Procedural nausea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Procedural pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Procedural site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Stoma site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinoatrial block			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Dizziness postural			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Loss of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Ophthalmic migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0

Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	6
Eosinophilia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Conjunctival oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Eye disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
Eye oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Eyelid oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Periorbital oedema			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	0 / 11 (0.00%)
occurrences (all)	1	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Anal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 12 (16.67%)	3 / 12 (25.00%)	1 / 11 (9.09%)
occurrences (all)	2	4	1
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 11 (9.09%)
occurrences (all)	0	3	1
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Faeces discoloured			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Lip blister			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	7 / 11 (63.64%)
occurrences (all)	4	0	8
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	2 / 12 (16.67%)	5 / 11 (45.45%)
occurrences (all)	3	2	6
Hepatobiliary disorders			
Bile duct stenosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	3	0
Jaundice			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Onychoclasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
Rash			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin fragility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vitiligo			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Xeroderma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Renal and urinary disorders			
Bladder spasm subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Chronic kidney disease subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Leukocyturia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Nocturia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Proteinuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0

Strangury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	2 / 11 (18.18%)
occurrences (all)	0	1	3
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	2	0

Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Clubbing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Joint stiffness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	0 / 11 (0.00%)
occurrences (all)	1	3	0

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	2 / 11 (18.18%) 2
Myopathy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	1 / 11 (9.09%) 1
Sarcopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Infections and infestations Bacteraemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Bronchitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Oral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	1 / 11 (9.09%)
occurrences (all)	1	2	1
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Folate deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P1A BMS150+NIV240	P1A ALL MONO	P1A BMS1200+NIV240
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)	45 / 59 (76.27%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Infected neoplasm subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Inferior vena cava stenosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	4 / 59 (6.78%)	2 / 7 (28.57%)
occurrences (all)	1	4	3
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Chest pain			

subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Device related thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	4 / 12 (33.33%)	3 / 59 (5.08%)	2 / 7 (28.57%)
occurrences (all)	4	3	2
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
Inflammation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 12 (8.33%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Infusion site joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 12 (8.33%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	3 / 12 (25.00%)	1 / 59 (1.69%)	5 / 7 (71.43%)
occurrences (all)	3	1	5
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	5 / 12 (41.67%) 6	1 / 59 (1.69%) 1	2 / 7 (28.57%) 3
Xerosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Testis discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 12 (33.33%)	3 / 59 (5.08%)	1 / 7 (14.29%)
occurrences (all)	4	3	1
Dysphonia			
subjects affected / exposed	2 / 12 (16.67%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	4 / 59 (6.78%)	2 / 7 (28.57%)
occurrences (all)	2	4	2
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0

Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Alanine aminotransferase increased			
subjects affected / exposed	2 / 12 (16.67%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Ammonia increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Amylase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Blood glucose decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate			

decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
White blood cell count increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Post procedural pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural site reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vascular access site rash subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Wound dehiscence subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac failure subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Mitral valve disease subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Sinoatrial block subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 59 (1.69%) 1	0 / 7 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 59 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Central nervous system mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 12 (8.33%)	9 / 59 (15.25%)	2 / 7 (28.57%)
occurrences (all)	1	9	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Loss of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Spinal cord compression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 12 (25.00%)	9 / 59 (15.25%)	0 / 7 (0.00%)
occurrences (all)	3	9	0
Eosinophilia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	2 / 12 (16.67%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Eye disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Eye oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Periorbital oedema			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Vision blurred			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 12 (16.67%)	2 / 59 (3.39%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Abdominal pain			

subjects affected / exposed	1 / 12 (8.33%)	5 / 59 (8.47%)	1 / 7 (14.29%)
occurrences (all)	1	6	4
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	2 / 12 (16.67%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 12 (25.00%)	4 / 59 (6.78%)	2 / 7 (28.57%)
occurrences (all)	3	4	2
Dental caries			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 12 (50.00%)	6 / 59 (10.17%)	3 / 7 (42.86%)
occurrences (all)	6	7	4
Dry mouth			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Epigastric discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Faeces discoloured			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Glossitis			

subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 12 (33.33%)	6 / 59 (10.17%)	1 / 7 (14.29%)
occurrences (all)	4	7	1
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	6 / 59 (10.17%)	0 / 7 (0.00%)
occurrences (all)	2	9	0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hepatic cytolysis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Dermatitis contact			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Lichenoid keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Rash			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	2 / 7 (28.57%)
occurrences (all)	1	1	3
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Skin fissures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin hypopigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Vitiligo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haematuria			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Strangury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 12 (25.00%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	3	3	0
Arthritis			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Bone pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Clubbing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Joint swelling			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Myopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Osteoarthritis			

subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	2 / 59 (3.39%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Sarcopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	2 / 12 (16.67%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Vaginal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 12 (50.00%)	3 / 59 (5.08%)	0 / 7 (0.00%)
occurrences (all)	6	3	0
Dehydration			

subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Folate deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Hypocalcaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Hypomagnesaemia			

subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Iron deficiency			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P1A BMS1600	P1B BMS1200+NIV360	P1B BMS150+NIV360
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	6 / 8 (75.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neoplasm malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Inferior vena cava stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	2 / 12 (16.67%)	2 / 8 (25.00%)	2 / 9 (22.22%)
occurrences (all)	2	2	2
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Facial pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	4 / 9 (44.44%)
occurrences (all)	1	1	4
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Infusion site joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	3 / 8 (37.50%)	2 / 9 (22.22%)
occurrences (all)	0	4	2
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Xerosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			

subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Testis discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	2 / 8 (25.00%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Sleep disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Product issues Device dislocation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 9 (11.11%) 1
Ammonia increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Amylase decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 9 (11.11%) 1
Blood alkaline phosphatase decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0

Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Blood triglycerides abnormal subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Glycosylated haemoglobin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Heart rate decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 9 (11.11%) 1
Weight increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Incision site pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Post procedural pruritus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Procedural nausea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Procedural pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vascular access site rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cardiac failure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinoatrial block			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dizziness postural			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 12 (25.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Ophthalmic migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 12 (25.00%)	3 / 8 (37.50%)	1 / 9 (11.11%)
occurrences (all)	3	3	1
Eosinophilia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	2 / 8 (25.00%)	1 / 9 (11.11%)
occurrences (all)	1	2	3
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Anal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Anal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	3 / 9 (33.33%)
occurrences (all)	0	1	3
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	2 / 9 (22.22%)
occurrences (all)	1	1	4
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Faeces discoloured			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lip blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	3 / 9 (33.33%)
occurrences (all)	1	2	5
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	5
Hepatobiliary disorders			
Bile duct stenosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Rash			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitiligo			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Strangury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 8 (25.00%)	3 / 9 (33.33%)
occurrences (all)	0	2	4

Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Clubbing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	1 / 9 (11.11%) 1
Myopathy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Sarcopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 9 (11.11%) 1
Infections and infestations Bacteraemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Bronchitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Localised infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	4
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Iron deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P1A ALL COMBO	P1A BMS1600+NIV240	P1B BMS1200+NIV480
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 52 (96.15%)	9 / 10 (90.00%)	6 / 7 (85.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Infected neoplasm subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	2 / 52 (3.85%) 2	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	2 / 52 (3.85%) 2	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Inferior vena cava stenosis			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 52 (11.54%)	3 / 10 (30.00%)	0 / 7 (0.00%)
occurrences (all)	7	3	0
Axillary pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chest pain			

subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	14 / 52 (26.92%)	0 / 10 (0.00%)	5 / 7 (71.43%)
occurrences (all)	15	0	5
Feeling cold			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Inflammation			

subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	4 / 52 (7.69%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	5	0	0
Infusion site joint swelling			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	3 / 52 (5.77%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Oedema			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	19 / 52 (36.54%)	3 / 10 (30.00%)	0 / 7 (0.00%)
occurrences (all)	19	3	0
Pain			
subjects affected / exposed	2 / 52 (3.85%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Peripheral swelling			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	10 / 52 (19.23%) 12	1 / 10 (10.00%) 1	2 / 7 (28.57%) 2
Xerosis subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Testis discomfort subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	14 / 52 (26.92%)	5 / 10 (50.00%)	2 / 7 (28.57%)
occurrences (all)	16	5	2
Dysphonia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Dyspnoea			
subjects affected / exposed	12 / 52 (23.08%)	3 / 10 (30.00%)	1 / 7 (14.29%)
occurrences (all)	12	3	1
Dyspnoea exertional			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	5 / 52 (9.62%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	5	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Pleural effusion			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pneumothorax			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Respiratory tract congestion			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Throat irritation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0

Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 52 (7.69%)	3 / 10 (30.00%)	1 / 7 (14.29%)
occurrences (all)	4	3	1
Confusional state			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Hallucination			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	7 / 52 (13.46%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	7	0	1
Restlessness			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	4 / 52 (7.69%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Ammonia increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Amylase decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	6	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Blood creatinine increased			
subjects affected / exposed	4 / 52 (7.69%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	6	0	1
Blood glucose decreased			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood pressure increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood triglycerides abnormal			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lipase decreased			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	10	1	1
Liver function test increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate			

decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	4 / 52 (7.69%)	0 / 10 (0.00%)	2 / 7 (28.57%)
occurrences (all)	4	0	2
Weight increased			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
White blood cell count increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Fall			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Post procedural pruritus			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Procedural site reaction			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Stoma site pain			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Vascular access site pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vascular access site rash subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Wound dehiscence subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac failure subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Mitral valve disease subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Sinoatrial block subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Central nervous system mass			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Dizziness postural			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Headache			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	4	1	1
Hypoaesthesia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Loss of consciousness			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Ophthalmic migraine			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Seizure			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Somnolence			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Spinal cord compression			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 52 (15.38%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	11	2	1
Eosinophilia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Conjunctival oedema			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Diplopia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Eye disorder			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0

Eye oedema			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Eyelid oedema			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Vision blurred			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Visual impairment			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Xerophthalmia			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Abdominal pain			

subjects affected / exposed	5 / 52 (9.62%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	8	0	2
Abdominal pain lower			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Cheilitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	11 / 52 (21.15%)	2 / 10 (20.00%)	3 / 7 (42.86%)
occurrences (all)	12	2	3
Dental caries			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	14 / 52 (26.92%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	16	2	2
Dry mouth			
subjects affected / exposed	6 / 52 (11.54%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	7	3	0
Dyspepsia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Dysphagia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Faeces discoloured			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorder			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal hypermotility			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Gingival pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Glossitis			

subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lip blister			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	13 / 52 (25.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	15	2	0
Odynophagia			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Oral disorder			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Paraesthesia oral			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			

subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Small intestinal haemorrhage			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	12 / 52 (23.08%)	3 / 10 (30.00%)	1 / 7 (14.29%)
occurrences (all)	14	4	1
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatic cytolysis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Jaundice			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Portal vein thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Dermatitis contact			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Ecchymosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Onychoclasia			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Pruritus			
subjects affected / exposed	5 / 52 (9.62%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	5	1	0
Rash			
subjects affected / exposed	5 / 52 (9.62%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	7	2	0
Rash macular			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Rash pruritic			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin fragility			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin hypopigmentation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Vitiligo			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematuria			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Strangury			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	5 / 52 (9.62%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	5	1	0

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 52 (13.46%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	9	2	0
Arthritis			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Back pain			
subjects affected / exposed	8 / 52 (15.38%)	4 / 10 (40.00%)	2 / 7 (28.57%)
occurrences (all)	8	4	2
Bone pain			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Clubbing			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Joint range of motion decreased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mobility decreased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	5 / 52 (9.62%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	5	1	0
Muscular weakness			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Musculoskeletal chest pain			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	3 / 52 (5.77%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Myopathy			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Osteoarthritis			

subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	4 / 52 (7.69%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Sarcopenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 52 (3.85%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Conjunctivitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Herpes virus infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 52 (5.77%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Onychomycosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	3 / 52 (5.77%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Pneumonia aspiration			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0

Sepsis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Tooth infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 52 (5.77%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Urinary tract infection			
subjects affected / exposed	4 / 52 (7.69%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Vaginal infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Wound infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	11 / 52 (21.15%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	11	2	0
Dehydration			

subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Folate deficiency			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	2 / 52 (3.85%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 52 (1.92%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	4	4	0
Hyperkalaemia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	4 / 52 (7.69%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	5	3	0
Hypocalcaemia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			

subjects affected / exposed	6 / 52 (11.54%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	6	2	0
Hyponatraemia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Hypophosphataemia			
subjects affected / exposed	2 / 52 (3.85%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	2	2	1
Iron deficiency			
subjects affected / exposed	1 / 52 (1.92%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P1B BMS1600SC	P1B ALL COMBO	P2 PANCREATIC COMBO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 18 (94.44%)	21 / 24 (87.50%)	17 / 19 (89.47%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neoplasm malignant			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	2	0	2
Inferior vena cava stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Vasculitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vena cava thrombosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Venous thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	1 / 18 (5.56%)	4 / 24 (16.67%)	5 / 19 (26.32%)
occurrences (all)	1	4	6
Axillary pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Catheter site pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	3 / 18 (16.67%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	3	1	0
Face oedema			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Facial pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	9 / 18 (50.00%)	10 / 24 (41.67%)	6 / 19 (31.58%)
occurrences (all)	9	10	6
Feeling cold			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Infusion site joint swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	2 / 18 (11.11%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
Oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	4 / 18 (22.22%)	5 / 24 (20.83%)	5 / 19 (26.32%)
occurrences (all)	5	6	5
Pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Peripheral swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	6 / 18 (33.33%)	2 / 24 (8.33%)	4 / 19 (21.05%)
occurrences (all)	7	2	4
Xerosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Testis discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 18 (16.67%)	3 / 24 (12.50%)	4 / 19 (21.05%)
occurrences (all)	3	3	4
Dysphonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	4 / 18 (22.22%)	4 / 24 (16.67%)	5 / 19 (26.32%)
occurrences (all)	4	4	5
Dyspnoea exertional			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hiccups			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Sinus congestion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 18 (11.11%)	2 / 24 (8.33%)	2 / 19 (10.53%)
occurrences (all)	2	2	2
Confusional state			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Restlessness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Sleep disorder subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Product issues Device dislocation subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	1 / 24 (4.17%) 1	3 / 19 (15.79%) 4
Ammonia increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Amylase decreased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 2	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 24 (4.17%) 1	5 / 19 (26.32%) 6
Blood alkaline phosphatase decreased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	3 / 19 (15.79%) 3

Blood cholesterol increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Blood glucose decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood iron decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Blood pressure increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Blood triglycerides abnormal subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Glycosylated haemoglobin increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Heart rate decreased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	7
Heart rate increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Hepatic enzyme increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	3 / 24 (12.50%) 3	1 / 19 (5.26%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Incision site pain subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	2 / 19 (10.53%) 2
Post procedural pruritus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Procedural nausea subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Procedural pain			

subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Procedural site reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Vascular access site rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Cardiac failure			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Mitral valve disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Sinoatrial block			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Dizziness			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Dizziness postural			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 18 (0.00%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Hypoaesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	1 / 18 (5.56%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Ophthalmic migraine			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Spinal cord compression			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 18 (11.11%)	5 / 24 (20.83%)	2 / 19 (10.53%)
occurrences (all)	2	5	2
Eosinophilia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			

subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Eye disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			

subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 24 (4.17%) 1	0 / 19 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Xerophthalmia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2	1 / 24 (4.17%) 1	0 / 19 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	7 / 18 (38.89%) 7	4 / 24 (16.67%) 7	4 / 19 (21.05%) 4
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	3 / 19 (15.79%) 3
Abdominal tenderness subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 24 (4.17%) 1	0 / 19 (0.00%) 0
Anal erythema subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0

Anal pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	2 / 18 (11.11%)	1 / 24 (4.17%)	7 / 19 (36.84%)
occurrences (all)	2	1	7
Cheilitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 18 (22.22%)	7 / 24 (29.17%)	4 / 19 (21.05%)
occurrences (all)	4	7	4
Dental caries			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 18 (11.11%)	4 / 24 (16.67%)	1 / 19 (5.26%)
occurrences (all)	2	7	2
Dry mouth			
subjects affected / exposed	0 / 18 (0.00%)	3 / 24 (12.50%)	1 / 19 (5.26%)
occurrences (all)	0	3	1
Dyspepsia			
subjects affected / exposed	1 / 18 (5.56%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Dysphagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Faeces discoloured			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Gingival pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Lip blister			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	5 / 18 (27.78%)	4 / 24 (16.67%)	4 / 19 (21.05%)
occurrences (all)	5	7	4
Odynophagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Paraesthesia oral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 18 (22.22%)	3 / 24 (12.50%)	3 / 19 (15.79%)
occurrences (all)	4	6	3
Hepatobiliary disorders			
Bile duct stenosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cholestasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Dermatitis contact			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 18 (0.00%)	3 / 24 (12.50%)	3 / 19 (15.79%)
occurrences (all)	0	3	3
Rash			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Rash macular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vitiligo			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Chromaturia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Strangury			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 18 (0.00%)	2 / 24 (8.33%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 18 (27.78%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	5	1	1
Arthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 18 (11.11%)	7 / 24 (29.17%)	1 / 19 (5.26%)
occurrences (all)	2	8	1

Bone pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Clubbing			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 18 (11.11%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Limb discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences (all)	1	1	1

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 24 (4.17%) 1	2 / 19 (10.53%) 2
Myopathy subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2	0 / 24 (0.00%) 0	3 / 19 (15.79%) 3
Sarcopenia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	0 / 19 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 24 (4.17%) 1	0 / 19 (0.00%) 0
Infections and infestations Bacteraemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 24 (0.00%) 0	1 / 19 (5.26%) 1
Bronchitis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Escherichia infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Localised infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Periodontitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 18 (0.00%)	2 / 24 (8.33%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Urinary tract infection			
subjects affected / exposed	1 / 18 (5.56%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Vaginal infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 18 (33.33%)	3 / 24 (12.50%)	6 / 19 (31.58%)
occurrences (all)	6	4	6
Dehydration			
subjects affected / exposed	2 / 18 (11.11%)	2 / 24 (8.33%)	2 / 19 (10.53%)
occurrences (all)	2	2	2
Folate deficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	3 / 24 (12.50%)	1 / 19 (5.26%)
occurrences (all)	1	3	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Hyperkalaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	1 / 18 (5.56%)	2 / 24 (8.33%)	4 / 19 (21.05%)
occurrences (all)	1	2	4
Hypophosphataemia			
subjects affected / exposed	1 / 18 (5.56%)	3 / 24 (12.50%)	2 / 19 (10.53%)
occurrences (all)	1	3	2
Iron deficiency			
subjects affected / exposed	1 / 18 (5.56%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P2 NSCLC COMBO	P2 MELANOMA COMBO	P2 2 SCCHN COMBO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 31 (100.00%)	14 / 15 (93.33%)	14 / 15 (93.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Infected neoplasm subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Hot flush subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 15 (6.67%) 1	3 / 15 (20.00%) 3
Inferior vena cava stenosis			

subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	14 / 31 (45.16%)	5 / 15 (33.33%)	1 / 15 (6.67%)
occurrences (all)	19	6	1
Axillary pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Facial pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 31 (19.35%)	1 / 15 (6.67%)	9 / 15 (60.00%)
occurrences (all)	6	3	9
Feeling cold			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Inflammation			

subjects affected / exposed	3 / 31 (9.68%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Influenza like illness			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Infusion site joint swelling			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 31 (9.68%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	3	0	4
Oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 31 (12.90%)	3 / 15 (20.00%)	2 / 15 (13.33%)
occurrences (all)	4	3	2
Pain			
subjects affected / exposed	2 / 31 (6.45%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Peripheral swelling			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	2 / 31 (6.45%) 3	3 / 15 (20.00%) 3	0 / 15 (0.00%) 0
Xerosis subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Testis discomfort subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	9 / 31 (29.03%)	3 / 15 (20.00%)	1 / 15 (6.67%)
occurrences (all)	12	3	1
Dysphonia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	11 / 31 (35.48%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	13	0	3
Dyspnoea exertional			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Hiccups			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Pleural effusion			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pleuritic pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	3 / 31 (9.68%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	3	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Confusional state			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 31 (6.45%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Restlessness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Product issues			
Device dislocation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Amylase decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	5 / 31 (16.13%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	7	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	6	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Blood cholesterol increased			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	5 / 31 (16.13%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	5	0	1
Blood glucose decreased			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	6 / 31 (19.35%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	8	1	1
Blood pressure increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Blood triglycerides abnormal			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Blood triglycerides increased			
subjects affected / exposed	2 / 31 (6.45%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Blood urea increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood uric acid increased			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Blood urine present			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	6 / 31 (19.35%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	7	2	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemoglobin increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Heart rate decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lipase decreased			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	8 / 31 (25.81%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	12	1	1
Liver function test increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Protein total decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate			

decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	3	1	2
Weight increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Post procedural pruritus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Procedural site reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Vascular access site rash subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Wound dehiscence subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Cardiac failure subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Mitral valve disease subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Sinoatrial block subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dizziness postural			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	3	1	4
Hypoaesthesia			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Loss of consciousness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	3 / 31 (9.68%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	3	0	1
Ophthalmic migraine			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Spinal cord compression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 31 (29.03%)	3 / 15 (20.00%)	3 / 15 (20.00%)
occurrences (all)	9	4	3
Eosinophilia			
subjects affected / exposed	2 / 31 (6.45%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Hyperleukocytosis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Lymphopenia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	5	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Vestibular disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eye disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Eye oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	2 / 31 (6.45%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	3	0	1
Abdominal tenderness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 31 (16.13%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	6	1	3
Dental caries			

subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	9 / 31 (29.03%)	4 / 15 (26.67%)	3 / 15 (20.00%)
occurrences (all)	15	4	4
Dry mouth			
subjects affected / exposed	2 / 31 (6.45%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
Dyspepsia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Dysphagia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Faeces discoloured			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Glossitis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	4	0	2
Odynophagia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oral disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Oral lichen planus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	4 / 31 (12.90%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	4	0	1
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Hepatic cytolysis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	2 / 31 (6.45%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Ecchymosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Lichenoid keratosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Onychoclasia			

subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 31 (9.68%)	3 / 15 (20.00%)	2 / 15 (13.33%)
occurrences (all)	3	3	2
Rash			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Rash macular			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
Rash pruritic			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Skin hypopigmentation			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin induration			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Xeroderma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Hydronephrosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Strangury			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Hypothyroidism			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 31 (12.90%)	2 / 15 (13.33%)	2 / 15 (13.33%)
occurrences (all)	4	3	2
Arthritis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	4	1	1
Bone pain			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Clubbing			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Limb discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	3 / 31 (9.68%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 31 (6.45%)	4 / 15 (26.67%)	2 / 15 (13.33%)
occurrences (all)	2	4	2
Myopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Osteoarthritis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	3	1	1
Sarcopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Trismus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Cystitis			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Ear infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 31 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Laryngitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	4 / 15 (26.67%)
occurrences (all)	1	0	5
Pneumonia aspiration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Propionibacterium infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Renal abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0

Sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Vaginal infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 31 (16.13%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	6	1	3
Dehydration			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 31 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	2
Hypercholesterolaemia			
subjects affected / exposed	8 / 31 (25.81%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	13	2	1
Hyperglycaemia			
subjects affected / exposed	8 / 31 (25.81%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	12	0	0
Hyperkalaemia			
subjects affected / exposed	5 / 31 (16.13%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	5	0	0
Hypertriglyceridaemia			
subjects affected / exposed	3 / 31 (9.68%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	5	2	1
Hyperuricaemia			
subjects affected / exposed	7 / 31 (22.58%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	10	2	0
Hypoalbuminaemia			
subjects affected / exposed	6 / 31 (19.35%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	7	3	0
Hypocalcaemia			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	1 / 31 (3.23%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	1	2	3
Hypomagnesaemia			

subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Hyponatraemia			
subjects affected / exposed	6 / 31 (19.35%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	6	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Iron deficiency			
subjects affected / exposed	1 / 31 (3.23%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P2 RCC COMBO	P2 RCC MONO	P2 RCC CROSSOVER
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 18 (94.44%)	19 / 19 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neoplasm malignant			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	3 / 18 (16.67%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Hypotension			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Inferior vena cava stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	2 / 18 (11.11%)	9 / 19 (47.37%)	0 / 3 (0.00%)
occurrences (all)	2	10	0
Axillary pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Facial pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	4 / 18 (22.22%)	4 / 19 (21.05%)	2 / 3 (66.67%)
occurrences (all)	5	7	2
Feeling cold			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Generalised oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperthermia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site joint swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 18 (11.11%)	4 / 19 (21.05%)	1 / 3 (33.33%)
occurrences (all)	2	4	1
Pain			
subjects affected / exposed	4 / 18 (22.22%)	2 / 19 (10.53%)	1 / 3 (33.33%)
occurrences (all)	4	2	1
Peripheral swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	3 / 19 (15.79%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Xerosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Testis discomfort			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 18 (11.11%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Dysphonia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 18 (11.11%)	5 / 19 (26.32%)	1 / 3 (33.33%)
occurrences (all)	2	7	1
Dyspnoea exertional			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Pleuritic pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Productive cough			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Restlessness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Sleep disorder subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Product issues Device dislocation subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	1 / 3 (33.33%) 1
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Ammonia increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Amylase decreased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 19 (5.26%) 1	0 / 3 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood alkaline phosphatase decreased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	1 / 3 (33.33%) 2
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0

Blood cholesterol increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	1 / 3 (33.33%)
occurrences (all)	2	3	2
Blood glucose decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Blood triglycerides abnormal subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	1 / 3 (33.33%) 2
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Glycosylated haemoglobin increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 19 (5.26%) 1	0 / 3 (0.00%) 0
Heart rate decreased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Lipase increased			
subjects affected / exposed	3 / 18 (16.67%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	5	2	0
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Monocyte count increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Neutrophil percentage increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Red blood cell sedimentation rate decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Red blood cells urine positive			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Troponin I increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	2 / 3 (66.67%) 2
Weight increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 2	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	1 / 3 (33.33%) 1
Incision site pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 19 (5.26%) 1	0 / 3 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Post procedural pruritus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Procedural nausea subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Procedural pain			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural site reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mitral valve disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinoatrial block			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Central nervous system mass			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dizziness			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Dizziness postural			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	3 / 18 (16.67%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Hypoaesthesia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Loss of consciousness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ophthalmic migraine			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 18 (22.22%)	2 / 19 (10.53%)	2 / 3 (66.67%)
occurrences (all)	4	2	2
Eosinophilia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vestibular disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 18 (0.00%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Ocular hyperaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 18 (5.56%)	4 / 19 (21.05%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Abdominal tenderness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Anal pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 18 (16.67%)	3 / 19 (15.79%)	0 / 3 (0.00%)
occurrences (all)	3	6	0
Dental caries			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	7 / 18 (38.89%)	6 / 19 (31.58%)	2 / 3 (66.67%)
occurrences (all)	9	8	3
Dry mouth			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Faeces discoloured			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Gingival pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lip blister			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	3 / 18 (16.67%)	2 / 19 (10.53%)	2 / 3 (66.67%)
occurrences (all)	3	3	2
Odynophagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 18 (11.11%)	3 / 19 (15.79%)	1 / 3 (33.33%)
occurrences (all)	3	3	1
Hepatobiliary disorders			
Bile duct stenosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Dermatitis contact			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Ecchymosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 18 (11.11%)	2 / 19 (10.53%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Rash			

subjects affected / exposed	2 / 18 (11.11%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Rash macular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitiligo			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Dysuria			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	3
Hydronephrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0

Strangury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperthyroidism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 18 (11.11%)	4 / 19 (21.05%)	0 / 3 (0.00%)
occurrences (all)	2	6	0
Arthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 18 (11.11%)	3 / 19 (15.79%)	2 / 3 (66.67%)
occurrences (all)	2	3	2

Bone pain			
subjects affected / exposed	0 / 18 (0.00%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Clubbing			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Coccydynia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Limb discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 18 (0.00%)	3 / 19 (15.79%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Muscular weakness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Myopathy subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	3 / 18 (16.67%) 3	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Sarcopenia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Infections and infestations Bacteraemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 19 (0.00%) 0	0 / 3 (0.00%) 0
Bronchitis			

subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Localised infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Purulent discharge			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 18 (0.00%)	2 / 19 (10.53%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	4 / 18 (22.22%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
Vaginal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 18 (16.67%)	5 / 19 (26.32%)	2 / 3 (66.67%)
occurrences (all)	3	7	2
Dehydration			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	2 / 18 (11.11%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Hyperkalaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 19 (5.26%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	2 / 18 (11.11%)	3 / 19 (15.79%)	1 / 3 (33.33%)
occurrences (all)	2	4	2
Iron deficiency			
subjects affected / exposed	1 / 18 (5.56%)	0 / 19 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P2 PROSTATE COMBO	P2 NOT ASSIGNED MONO	P2 NOT ASSIGNED COMBO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 14 (92.86%)	1 / 1 (100.00%)	1 / 2 (50.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Infected neoplasm subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	4 / 14 (28.57%) 4	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 1 (100.00%) 1	0 / 2 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Inferior vena cava stenosis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	2
Axillary pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 14 (28.57%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Feeling cold			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Inflammation			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Infusion site joint swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Xerosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Testis discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 14 (21.43%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Laryngeal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Amylase decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Blood glucose decreased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haemoglobin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neutrophil percentage increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Red blood cell sedimentation rate			

decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
White blood cells urine positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Post procedural pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural site reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vascular access site rash subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Wound dehiscence subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Cardiac failure subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Mitral valve disease subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Sinoatrial block subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders			
Amnesia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Aphasia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Burning sensation			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Carpal tunnel syndrome			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Central nervous system mass			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Dizziness			
subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Dizziness postural			
subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Dysarthria			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Dysgeusia			
subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Headache			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Hypoaesthesia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0

Loss of consciousness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Eosinophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			

subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Eye oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			

subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Anal pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 14 (28.57%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	6	1	0
Dental caries			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glossitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Odynophagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral lichen planus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 14 (21.43%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Rash			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin fragility			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Skin hypopigmentation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chronic kidney disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 14 (21.43%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	4	1	0
Arthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 14 (14.29%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clubbing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Myopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Sarcopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nasal herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Propionibacterium infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dehydration			

subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hyperkalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P2 ALL COMBO	ALL COMBO (P1A+P1B+P2)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	110 / 117 (94.02%)	181 / 193 (93.78%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Neoplasm malignant			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Tumour pain			
subjects affected / exposed	6 / 117 (5.13%)	9 / 193 (4.66%)	
occurrences (all)	6	9	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Embolism			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Haematoma			

subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Haemorrhage			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Hot flush			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences (all)	3	3	
Hypertension			
subjects affected / exposed	5 / 117 (4.27%)	7 / 193 (3.63%)	
occurrences (all)	6	8	
Hypotension			
subjects affected / exposed	7 / 117 (5.98%)	8 / 193 (4.15%)	
occurrences (all)	7	8	
Inferior vena cava stenosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Lymphoedema			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Orthostatic hypotension			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences (all)	2	2	
Thrombosis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Vasculitis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Vena cava thrombosis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Venous thrombosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	30 / 117 (25.64%)	40 / 193 (20.73%)	
occurrences (all)	38	49	
Axillary pain			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Catheter site pain			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Chest discomfort			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Chest pain			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Chills			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Device related thrombosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Discomfort			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Early satiety			
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)	
occurrences (all)	0	2	
Face oedema			
subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)	
occurrences (all)	2	4	
Facial pain			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Fatigue			

subjects affected / exposed	32 / 117 (27.35%)	56 / 193 (29.02%)
occurrences (all)	35	60
Feeling cold		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Gait disturbance		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Generalised oedema		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Hyperthermia		
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)
occurrences (all)	3	5
Inflammation		
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)
occurrences (all)	3	4
Influenza like illness		
subjects affected / exposed	2 / 117 (1.71%)	7 / 193 (3.63%)
occurrences (all)	3	9
Infusion site joint swelling		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Injection site reaction		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Localised oedema		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3
Malaise		
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)
occurrences (all)	0	3
Mucosal inflammation		
subjects affected / exposed	3 / 117 (2.56%)	6 / 193 (3.11%)
occurrences (all)	3	6
Non-cardiac chest pain		

subjects affected / exposed	8 / 117 (6.84%)	11 / 193 (5.70%)	
occurrences (all)	9	12	
Oedema			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Oedema peripheral			
subjects affected / exposed	19 / 117 (16.24%)	43 / 193 (22.28%)	
occurrences (all)	19	44	
Pain			
subjects affected / exposed	10 / 117 (8.55%)	12 / 193 (6.22%)	
occurrences (all)	11	13	
Peripheral swelling			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	12 / 117 (10.26%)	24 / 193 (12.44%)	
occurrences (all)	13	27	
Xerosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Intermenstrual bleeding			

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Pelvic pain			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Testis discomfort			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Vaginal discharge			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Vaginal haemorrhage			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Cough			
subjects affected / exposed	22 / 117 (18.80%)	39 / 193 (20.21%)	
occurrences (all)	26	45	
Dysphonia			
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)	
occurrences (all)	1	3	
Dyspnoea			
subjects affected / exposed	26 / 117 (22.22%)	42 / 193 (21.76%)	
occurrences (all)	28	44	
Dyspnoea exertional			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences (all)	2	3	
Haemoptysis			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences (all)	3	3	
Hiccups			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Hypoxia		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Interstitial lung disease		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Laryngeal haemorrhage		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Nasal congestion		
subjects affected / exposed	1 / 117 (0.85%)	7 / 193 (3.63%)
occurrences (all)	1	7
Oropharyngeal pain		
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)
occurrences (all)	1	3
Pleural effusion		
subjects affected / exposed	3 / 117 (2.56%)	5 / 193 (2.59%)
occurrences (all)	3	5
Pleuritic pain		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Pneumonitis		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3
Pneumothorax		
subjects affected / exposed	4 / 117 (3.42%)	4 / 193 (2.07%)
occurrences (all)	4	4
Productive cough		
subjects affected / exposed	5 / 117 (4.27%)	7 / 193 (3.63%)
occurrences (all)	5	7
Pulmonary embolism		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Respiratory tract congestion		

subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Sinus congestion			
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)	
occurrences (all)	0	2	
Throat irritation			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Upper respiratory tract inflammation			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Upper-airway cough syndrome			
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)	
occurrences (all)	1	3	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	6 / 117 (5.13%)	12 / 193 (6.22%)	
occurrences (all)	6	12	
Confusional state			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Depression			
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)	
occurrences (all)	1	3	
Hallucination			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	5 / 117 (4.27%)	13 / 193 (6.74%)	
occurrences (all)	5	13	
Restlessness			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	

Sleep disorder subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	2 / 193 (1.04%) 2	
Product issues Device dislocation subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	3 / 193 (1.55%) 3	
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 117 (2.56%) 4	8 / 193 (4.15%) 9	
Ammonia increased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Amylase decreased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Amylase increased subjects affected / exposed occurrences (all)	7 / 117 (5.98%) 9	11 / 193 (5.70%) 15	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	9 / 117 (7.69%) 10	12 / 193 (6.22%) 13	
Blood alkaline phosphatase decreased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	8 / 117 (6.84%) 11	10 / 193 (5.18%) 13	
Blood bilirubin increased subjects affected / exposed occurrences (all)	4 / 117 (3.42%) 5	5 / 193 (2.59%) 7	

Blood cholesterol increased		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Blood creatine phosphokinase MB increased		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	2
Blood creatine phosphokinase decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Blood creatine phosphokinase increased		
subjects affected / exposed	3 / 117 (2.56%)	6 / 193 (3.11%)
occurrences (all)	3	7
Blood creatinine increased		
subjects affected / exposed	8 / 117 (6.84%)	13 / 193 (6.74%)
occurrences (all)	10	17
Blood glucose decreased		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Blood iron decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Blood lactate dehydrogenase increased		
subjects affected / exposed	8 / 117 (6.84%)	9 / 193 (4.66%)
occurrences (all)	10	11
Blood pressure increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Blood thyroid stimulating hormone decreased		
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)
occurrences (all)	4	4
Blood thyroid stimulating hormone increased		
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)
occurrences (all)	3	5

Blood triglycerides abnormal subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	2 / 193 (1.04%) 2	
Blood triglycerides increased subjects affected / exposed occurrences (all)	4 / 117 (3.42%) 4	4 / 193 (2.07%) 4	
Blood urea increased subjects affected / exposed occurrences (all)	4 / 117 (3.42%) 4	4 / 193 (2.07%) 4	
Blood uric acid increased subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	2 / 193 (1.04%) 2	
Blood urine present subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
C-reactive protein increased subjects affected / exposed occurrences (all)	3 / 117 (2.56%) 3	3 / 193 (1.55%) 3	
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	10 / 117 (8.55%) 12	12 / 193 (6.22%) 14	
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Glycosylated haemoglobin increased subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	2 / 193 (1.04%) 2	
Haemoglobin increased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Heart rate decreased			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	7	7
Heart rate increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	2	2
Hepatic enzyme increased		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Immature granulocyte count increased		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
International normalised ratio increased		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Lipase decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	2	2
Lipase increased		
subjects affected / exposed	14 / 117 (11.97%)	19 / 193 (9.84%)
occurrences (all)	20	31
Liver function test increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	2	2
Lymphocyte count decreased		
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)
occurrences (all)	5	5
Lymphocyte percentage decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Monocyte count increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Neutrophil count decreased		

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Neutrophil count increased		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	3	4
Neutrophil percentage increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Platelet count decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Protein total decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	2	2
Red blood cell count decreased		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Red blood cell sedimentation rate decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Red blood cells urine positive		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
SARS-CoV-2 test positive		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Transaminases increased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Tri-iodothyronine free decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Troponin I increased		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1

Urine leukocyte esterase positive subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Weight decreased subjects affected / exposed occurrences (all)	9 / 117 (7.69%) 9	16 / 193 (8.29%) 16	
Weight increased subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	2 / 193 (1.04%) 3	
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 2	2 / 193 (1.04%) 3	
White blood cells urine positive subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	2 / 193 (1.04%) 4	
Fall subjects affected / exposed occurrences (all)	3 / 117 (2.56%) 3	3 / 193 (1.55%) 3	
Incision site pain subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Infusion related reaction subjects affected / exposed occurrences (all)	6 / 117 (5.13%) 6	8 / 193 (4.15%) 8	
Post procedural pruritus subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Procedural nausea subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Procedural pain			

subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 2	3 / 193 (1.55%) 3	
Procedural site reaction subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Rib fracture subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Skin abrasion subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Stoma site pain subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Vascular access site pain subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Vascular access site rash subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Wound subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Wound dehiscence subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Cardiac failure			

subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences (all)	2	2	
Mitral valve disease			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Palpitations			
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)	
occurrences (all)	3	4	
Sinoatrial block			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Sinus bradycardia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Tachycardia			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Aphasia			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Burning sensation			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)	
occurrences (all)	0	2	
Central nervous system mass			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	

Dizziness		
subjects affected / exposed	4 / 117 (3.42%)	6 / 193 (3.11%)
occurrences (all)	4	7
Dizziness postural		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	2	2
Dysarthria		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Dysgeusia		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3
Headache		
subjects affected / exposed	10 / 117 (8.55%)	16 / 193 (8.29%)
occurrences (all)	11	18
Hypoaesthesia		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3
Loss of consciousness		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Memory impairment		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Neuropathy peripheral		
subjects affected / exposed	4 / 117 (3.42%)	8 / 193 (4.15%)
occurrences (all)	4	8
Ophthalmic migraine		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Paraesthesia		
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)
occurrences (all)	3	4
Peripheral sensory neuropathy		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2

Presyncope			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Restless legs syndrome			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Seizure			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)	
occurrences (all)	3	4	
Spinal cord compression			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Taste disorder			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Tremor			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	25 / 117 (21.37%)	38 / 193 (19.69%)	
occurrences (all)	26	42	
Eosinophilia			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences (all)	4	4	
Hyperleukocytosis			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences (all)	2	2	
Iron deficiency anaemia			

subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences (all)	2	2	
Lymphopenia			
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)	
occurrences (all)	2	2	
Splenic vein thrombosis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Thrombocytosis			
subjects affected / exposed	4 / 117 (3.42%)	4 / 193 (2.07%)	
occurrences (all)	5	5	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Middle ear effusion			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Middle ear inflammation			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Tinnitus			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences (all)	3	3	
Vestibular disorder			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Eye disorders			
Amaurosis			

subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Conjunctival haemorrhage		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Conjunctival oedema		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Diplopia		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Dry eye		
subjects affected / exposed	1 / 117 (0.85%)	4 / 193 (2.07%)
occurrences (all)	1	4
Eye disorder		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Eye irritation		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	3
Eye oedema		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Eye pruritus		
subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)
occurrences (all)	0	3
Eyelid oedema		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Lacrimation increased		
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)
occurrences (all)	0	2
Ocular hyperaemia		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Periorbital oedema		

subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)	
occurrences (all)	0	4	
Vision blurred			
subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)	
occurrences (all)	0	3	
Visual impairment			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Xerophthalmia			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	2 / 117 (1.71%)	7 / 193 (3.63%)	
occurrences (all)	2	7	
Abdominal pain			
subjects affected / exposed	11 / 117 (9.40%)	20 / 193 (10.36%)	
occurrences (all)	12	27	
Abdominal pain lower			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Abdominal pain upper			
subjects affected / exposed	7 / 117 (5.98%)	11 / 193 (5.70%)	
occurrences (all)	8	12	
Abdominal tenderness			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Anal erythema			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Anal haemorrhage			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	

Anal pruritus		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Aphthous ulcer		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Ascites		
subjects affected / exposed	7 / 117 (5.98%)	10 / 193 (5.18%)
occurrences (all)	7	10
Cheilitis		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Colitis		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Constipation		
subjects affected / exposed	19 / 117 (16.24%)	37 / 193 (19.17%)
occurrences (all)	23	42
Dental caries		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Diarrhoea		
subjects affected / exposed	27 / 117 (23.08%)	45 / 193 (23.32%)
occurrences (all)	39	62
Dry mouth		
subjects affected / exposed	6 / 117 (5.13%)	15 / 193 (7.77%)
occurrences (all)	6	16
Dyspepsia		
subjects affected / exposed	1 / 117 (0.85%)	4 / 193 (2.07%)
occurrences (all)	2	5
Dysphagia		
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)
occurrences (all)	3	3
Epigastric discomfort		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2

Faeces discoloured		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Flatulence		
subjects affected / exposed	1 / 117 (0.85%)	4 / 193 (2.07%)
occurrences (all)	1	4
Gastrointestinal disorder		
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)
occurrences (all)	0	2
Gastrointestinal hypermotility		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Gastrooesophageal reflux disease		
subjects affected / exposed	4 / 117 (3.42%)	7 / 193 (3.63%)
occurrences (all)	4	7
Gingival pain		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Glossitis		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Haemorrhoids		
subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)
occurrences (all)	2	4
Lip blister		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Melaena		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Mouth ulceration		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1

Nausea			
subjects affected / exposed	17 / 117 (14.53%)	34 / 193 (17.62%)	
occurrences (all)	18	40	
Odynophagia			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	3	
Oral disorder			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Oral lichen planus			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences (all)	2	3	
Paraesthesia oral			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Proctalgia			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Rectal haemorrhage			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences (all)	2	3	
Toothache			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Vomiting			
subjects affected / exposed	11 / 117 (9.40%)	26 / 193 (13.47%)	
occurrences (all)	12	32	
Hepatobiliary disorders			
Bile duct stenosis			

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Cholestasis			
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)	
occurrences (all)	2	3	
Hepatic cytolysis			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Hypertransaminasaemia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	3	
Jaundice			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Portal vein thrombosis			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Blister			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Decubitus ulcer			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)	
occurrences (all)	1	4	
Dermatitis contact			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	

Dry skin		
subjects affected / exposed	6 / 117 (5.13%)	10 / 193 (5.18%)
occurrences (all)	6	10
Ecchymosis		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Erythema		
subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)
occurrences (all)	0	3
Hyperhidrosis		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Lichenoid keratosis		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Night sweats		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3
Onychoclasia		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Pain of skin		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Palmar-plantar erythrodysesthesia syndrome		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Photosensitivity reaction		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Pruritus		
subjects affected / exposed	17 / 117 (14.53%)	25 / 193 (12.95%)
occurrences (all)	17	25
Rash		

subjects affected / exposed	8 / 117 (6.84%)	13 / 193 (6.74%)
occurrences (all)	8	15
Rash macular		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Rash maculo-papular		
subjects affected / exposed	4 / 117 (3.42%)	7 / 193 (3.63%)
occurrences (all)	4	7
Rash pruritic		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Skin fissures		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Skin fragility		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Skin hyperpigmentation		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Skin hypopigmentation		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Skin induration		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Skin lesion		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Skin ulcer		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Urticaria		
subjects affected / exposed	1 / 117 (0.85%)	3 / 193 (1.55%)
occurrences (all)	1	3
Vitiligo		

subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Xeroderma subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Renal and urinary disorders			
Bladder spasm subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Chromaturia subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Chronic kidney disease subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 2	1 / 193 (0.52%) 2	
Dysuria subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	2 / 193 (1.04%) 2	
Haematuria subjects affected / exposed occurrences (all)	5 / 117 (4.27%) 8	5 / 193 (2.59%) 8	
Hydronephrosis subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Leukocyturia subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Nocturia subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Pollakiuria subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Proteinuria subjects affected / exposed occurrences (all)	2 / 117 (1.71%) 3	3 / 193 (1.55%) 4	

Strangury			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Urinary incontinence			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Urinary retention			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Hyperthyroidism			
subjects affected / exposed	3 / 117 (2.56%)	4 / 193 (2.07%)	
occurrences (all)	3	4	
Hypothyroidism			
subjects affected / exposed	4 / 117 (3.42%)	11 / 193 (5.70%)	
occurrences (all)	5	12	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)	
occurrences (all)	0	0	
Secondary adrenocortical insufficiency			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 117 (11.97%)	22 / 193 (11.40%)	
occurrences (all)	16	26	
Arthritis			
subjects affected / exposed	0 / 117 (0.00%)	3 / 193 (1.55%)	
occurrences (all)	0	3	
Back pain			
subjects affected / exposed	12 / 117 (10.26%)	27 / 193 (13.99%)	
occurrences (all)	13	29	

Bone pain		
subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)
occurrences (all)	2	4
Clubbing		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Coccydynia		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Flank pain		
subjects affected / exposed	1 / 117 (0.85%)	4 / 193 (2.07%)
occurrences (all)	1	5
Joint range of motion decreased		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Joint stiffness		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Joint swelling		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Limb discomfort		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Mobility decreased		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Muscle spasms		
subjects affected / exposed	4 / 117 (3.42%)	9 / 193 (4.66%)
occurrences (all)	5	10
Muscular weakness		
subjects affected / exposed	4 / 117 (3.42%)	7 / 193 (3.63%)
occurrences (all)	4	7
Musculoskeletal chest pain		
subjects affected / exposed	4 / 117 (3.42%)	8 / 193 (4.15%)
occurrences (all)	4	8

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	0 / 193 (0.00%) 0	
Musculoskeletal pain subjects affected / exposed occurrences (all)	4 / 117 (3.42%) 4	5 / 193 (2.59%) 5	
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Myalgia subjects affected / exposed occurrences (all)	13 / 117 (11.11%) 13	17 / 193 (8.81%) 17	
Myopathy subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Neck pain subjects affected / exposed occurrences (all)	3 / 117 (2.56%) 3	5 / 193 (2.59%) 6	
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 117 (0.00%) 0	1 / 193 (0.52%) 1	
Pain in extremity subjects affected / exposed occurrences (all)	11 / 117 (9.40%) 11	15 / 193 (7.77%) 15	
Sarcopenia subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Trismus subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	2 / 193 (1.04%) 2	
Infections and infestations Bacteraemia subjects affected / exposed occurrences (all)	1 / 117 (0.85%) 1	1 / 193 (0.52%) 1	
Bronchitis			

subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)
occurrences (all)	2	4
Conjunctivitis		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Cystitis		
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)
occurrences (all)	3	3
Ear infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Escherichia infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Fungal infection		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Furuncle		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Herpes virus infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Herpes zoster		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Influenza		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Laryngitis		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Localised infection		

subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Mucosal infection		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Nail infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Nasal herpes		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Nasopharyngitis		
subjects affected / exposed	1 / 117 (0.85%)	4 / 193 (2.07%)
occurrences (all)	1	4
Onychomycosis		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Oral candidiasis		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Oral herpes		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Oral infection		
subjects affected / exposed	2 / 117 (1.71%)	2 / 193 (1.04%)
occurrences (all)	2	2
Otitis externa		
subjects affected / exposed	0 / 117 (0.00%)	2 / 193 (1.04%)
occurrences (all)	0	2
Periodontitis		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Pharyngitis		
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)
occurrences (all)	0	1
Pneumonia		

subjects affected / exposed	5 / 117 (4.27%)	8 / 193 (4.15%)
occurrences (all)	6	9
Pneumonia aspiration		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Propionibacterium infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Purulent discharge		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Renal abscess		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Respiratory tract infection viral		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Rhinitis		
subjects affected / exposed	2 / 117 (1.71%)	4 / 193 (2.07%)
occurrences (all)	2	4
Sepsis		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Sinusitis		
subjects affected / exposed	0 / 117 (0.00%)	0 / 193 (0.00%)
occurrences (all)	0	0
Skin infection		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Tooth abscess		
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)
occurrences (all)	1	2
Tooth infection		
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)
occurrences (all)	1	1
Upper respiratory tract infection		

subjects affected / exposed	3 / 117 (2.56%)	8 / 193 (4.15%)	
occurrences (all)	3	8	
Urinary tract infection			
subjects affected / exposed	7 / 117 (5.98%)	12 / 193 (6.22%)	
occurrences (all)	7	12	
Vaginal infection			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Viral infection			
subjects affected / exposed	1 / 117 (0.85%)	2 / 193 (1.04%)	
occurrences (all)	1	2	
Wound infection			
subjects affected / exposed	1 / 117 (0.85%)	1 / 193 (0.52%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	21 / 117 (17.95%)	35 / 193 (18.13%)	
occurrences (all)	22	37	
Dehydration			
subjects affected / exposed	4 / 117 (3.42%)	8 / 193 (4.15%)	
occurrences (all)	4	8	
Folate deficiency			
subjects affected / exposed	3 / 117 (2.56%)	3 / 193 (1.55%)	
occurrences (all)	3	3	
Glucose tolerance impaired			
subjects affected / exposed	0 / 117 (0.00%)	1 / 193 (0.52%)	
occurrences (all)	0	1	
Hypercalcaemia			
subjects affected / exposed	5 / 117 (4.27%)	10 / 193 (5.18%)	
occurrences (all)	7	12	
Hypercholesterolaemia			
subjects affected / exposed	11 / 117 (9.40%)	11 / 193 (5.70%)	
occurrences (all)	16	16	
Hyperglycaemia			
subjects affected / exposed	8 / 117 (6.84%)	9 / 193 (4.66%)	
occurrences (all)	12	16	

Hyperkalaemia		
subjects affected / exposed	5 / 117 (4.27%)	7 / 193 (3.63%)
occurrences (all)	5	7
Hypertriglyceridaemia		
subjects affected / exposed	5 / 117 (4.27%)	5 / 193 (2.59%)
occurrences (all)	8	8
Hyperuricaemia		
subjects affected / exposed	8 / 117 (6.84%)	8 / 193 (4.15%)
occurrences (all)	12	12
Hypoalbuminaemia		
subjects affected / exposed	12 / 117 (10.26%)	16 / 193 (8.29%)
occurrences (all)	15	20
Hypocalcaemia		
subjects affected / exposed	3 / 117 (2.56%)	5 / 193 (2.59%)
occurrences (all)	3	5
Hypokalaemia		
subjects affected / exposed	4 / 117 (3.42%)	5 / 193 (2.59%)
occurrences (all)	6	7
Hypomagnesaemia		
subjects affected / exposed	6 / 117 (5.13%)	12 / 193 (6.22%)
occurrences (all)	6	12
Hyponatraemia		
subjects affected / exposed	12 / 117 (10.26%)	16 / 193 (8.29%)
occurrences (all)	12	16
Hypophosphataemia		
subjects affected / exposed	7 / 117 (5.98%)	12 / 193 (6.22%)
occurrences (all)	8	13
Iron deficiency		
subjects affected / exposed	2 / 117 (1.71%)	3 / 193 (1.55%)
occurrences (all)	2	3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 April 2016	<ol style="list-style-type: none"> 1) Added rationale for sentinel subject approach 2) Added additional rationales for 6 weeks DLT in dose escalation, and for initiation of PD substudy 3) Revised treatment arms and sample sizes for PD substudy 4) Revised vital sign measurements during infusions 5) Procedure clarifications and typographic changes
31 May 2016	<ol style="list-style-type: none"> 1) Revised Target Population in Inclusion Criteria in Section 3.3.1 2) Revised Dose-limiting Toxicities in Section 4.5.1
06 June 2016	<ol style="list-style-type: none"> 1) Clarified rationales for 2 week lead-in and for dose selection in Sections 1.1.3 and 1.1.5.1, respectively 2) Added a 9 day waiting period for doses over 400 mg, and revised waiting periods for each dose level Sections 1.1.7 and 3.1.1, respectively 3) Clarified definition of treatment arm and number of arms in Part 1B in Sections 3.1.2 and 8.3.1 4) Clarified requirement for dose delay in Part 1A in Section 4.5.4 5) Added language to allow for collection and central review of imaging assessments in Section 5.4 6) Editorial changes throughout the protocol
26 October 2016	<ol style="list-style-type: none"> 1) Included updates made in nivolumab IBv15 in Sections 1.4.4, 3.3.1, and Appendix 1, respectively 2) Added text describing vascular effects in mouse models in literature, and added dose delay in Section 1.5 3) Prohibited use of dipyridamole 2 weeks prior to the first dose and during treatment in Section 3.4.1 4) Removed windows for dosing visits and further clarified minimum treatment interval between 2 doses in Sections 5.1 and 4.5, respectively 5) Revised and clarified requirements for minimum dosing interval, dose delay due to toxicity, medical events or non-medical events, hepatic nonhematologic DLT, and removed tumor assessment procedure when study drugs are permanently discontinued in Section 4.5 6) In Section 5.1, revised Vital Signs requirements during initial treatment and re-treatment in Parts 1B and 2, removed pregnancy test on Days 8 and 22 during retreatment in Q1W, and added windows for tumor assessment during follow-ups 7) Clarified DILI criteria for subjects with abnormal ALT or AST at baseline in Section 6.6 8) Added 1 new reference in Section 12 9) Editorial changes throughout the protocol
16 March 2017	Incorporates Administrative Letters 01 and 02, and Amendments 01, 02, 03, 05 and 07
16 March 2017	<ol style="list-style-type: none"> 1) Included additional exclusion criteria for cardiovascular and cerebrovascular disease in Section 3.1.2 2) Added a new Section 3.4.4 to ensure appropriate assessment and management of cardiovascular risk factors 3) Updated dose delay criteria for subjects with any investigation or symptoms suggestive of possible thrombotic or ischemic events during treatment in Section 4.5.4.1 4) Updated guidelines to permanently discontinue BMS-986179 in subjects with any myocardial infarction or thrombotic/ischemic cerebrovascular event during treatment in Section 4.5.6

20 October 2017	<ol style="list-style-type: none"> 1) Changed the tumor types in Part 2, Cohort Expansion to add nonsmall cell lung cancer (NSCLC), renal cell cancer (RCC), castrateresistant prostate carcinoma, squamous cell carcinoma of the head and neck, and melanoma, and to delete ovarian cancer, colorectal cancer, and gastric cancer 2) Allowed for monotherapy in Part 2 with BMS-986179 in NSCLC and RCC, with the option for subjects to receive combination therapy with BMS-986179 and nivolumab at disease progression 3) Changed the treatment duration to 2 years, changed follow-up to 3 years after initial dose, and added a Q4W regimen for combination therapy with BMS-986179 and nivolumab 4) Added plasma sample collection for ctDNA extraction for assessment of tumor mutational burden in Section 5.7.1.6 5) Added laboratory parameters HbA1c, cardiovascular lipid profile, and PSA to list of assessments in Section 5.3.2 6) Added clinical observations and supporting data throughout Section 1.1 7) Added a replacement criterion to allow subjects without both pre- and on-treatment tumor biopsies, or whose biopsies are uninformative, to be replaced 8) Increased the number of pre-treatment core biopsy specimens from 2 to either 4 (for NSCLC, melanoma, and SCCHN) or 3 (for all other tumor types) 9) Changed the name of the Study Director/Medical Monitor 10) Editorial changes throughout the protocol
28 February 2018	<ol style="list-style-type: none"> 1) Subcutaneous dosing objective has been added to Part 1B of this study to assess a potentially important alternative approach to dosing. 2) Added background for rHuPH20, which enables SC administration of BMS-986179. 3) Sections added or modified based on addition of objective to assess tumors using iRECIST criteria by BICR. 4) New PK tables were added to support assessment for PK in subjects receiving subcutaneous dose.
30 November 2018	<ol style="list-style-type: none"> 1) Selection strategy has been modified based on new data on adenosineaxis that is more specific to the pathway being targeted by BMS-986179. 2) Data from completed toxicokinetics study has been added to provide additional safety information. 3) Part 2 expansion cohorts in the tumor-specific indications with high unmet medical need are open. Cardiovascular disease is prevalent in these indications. 4) Cardiovascular exclusion criteria has been modified. Under this modification, some asymptomatic patients with history of cardiovascular disease may be permitted to enroll after mandatory evaluation by specialist that includes functional ischemic test.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported