Clinical trial results:
A Phase 1/2 Multicenter Study of BMS-986012 in Subjects with Relapsed/Refractory Small Cell Lung Cancer

Summary

EudraCT number	2014-002372-89
Trial protocol	BE NL
Global end of trial date	21 December 2022

Results information

Result version number	v1 (current)
This version publication date	04 January 2024
First version publication date	04 January 2024

Trial information

Trial identification

Sponsor protocol code	CA001-030

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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	28 February 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 December 2022
Global end of trial reached?	Yes
Global end of trial date	21 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the multidose safety of BMS-986012 administered as monotherapy and in combination with nivolumab in subjects with relapsed/refractory small cell lung cancer (SCLC).

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Canada: 46
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 3
Country: Number of subjects enrolled	Netherlands: 4
Country: Number of subjects enrolled	Puerto Rico: 2
Country: Number of subjects enrolled	United States: 23
Worldwide total number of subjects	106
EEA total number of subjects	13

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)	59
From 65 to 84 years	47
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

106 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
Arm title	BMS 70mg

Arm description:

70 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

70 mg every 21 days

Arm title	BMS 160mg

Arm description:

160 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

160 mg every 21 days

Arm title	BMS 400mg

Arm description:

400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

400 mg every 21 days

Arm title	BMS 1000mg

Arm description:

1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg every 21 days

Arm title	BMS 400mg + Nivo 360mg

Arm description:

400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

360 mg every 21 days

Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

400 mg every 21 days

Arm title	BMS 1000mg + Nivo 360mg

Arm description:

1000 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

360 mg every 21 days

Investigational medicinal product name	BMS-986012
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg every 21 days

Number of subjects in period 1	BMS 70mg	BMS 160mg	BMS 400mg
Started	7	6	29
Completed	0	0	0
Not completed	7	6	29
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	-
Adverse Event unrelated to study drug	-	-	-
Study drug toxicity	-	1	1
Other reasons	-	-	1
Disease Progression	7	4	26
Participant request to discontinue study treatment	-	-	1
Administrative reason by sponsor	-	-	-

Number of subjects in period 1	BMS 1000mg	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg
Started	35	21	8
Completed	0	0	0
Not completed	35	21	8
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	-	-	-
Adverse Event unrelated to study drug	-	1	-
Study drug toxicity	1	2	2
Other reasons	-	-	-
Disease Progression	31	16	6
Participant request to discontinue study treatment	2	1	-
Administrative reason by sponsor	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	BMS 70mg
Reporting group description:	
70 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 160mg
Reporting group description:	
160 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg + Nivo 360mg
Reporting group description:	
400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg + Nivo 360mg
Reporting group description:	
1000 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met	

Reporting group values	BMS 70mg	BMS 160mg	BMS 400mg
Number of subjects	7	6	29
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	65.1	58.3	64.4
standard deviation	± 10.6	± 8.1	± 9.2
Sex: Female, Male Units: Participants			
Female	4	4	11
Male	3	2	18
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	7	6	27
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1

Not Hispanic or Latino	6	6	26
Unknown or Not Reported	0	0	2

Reporting group values	BMS 1000mg	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg
Number of subjects	35	21	8
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	61.7	62.1	61.1
standard deviation	± 9.5	± 9.8	± 7.3
Sex: Female, Male Units: Participants			
Female	12	9	5
Male	23	12	3
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	30	21	8
More than one race	0	0	0
Unknown or Not Reported	2	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	33	20	8
Unknown or Not Reported	2	0	0

Reporting group values	Total		
Number of subjects	106		
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	45		
Male	61		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	4		

Native Hawaiian or Other Pacific Islander	0		
Black or African American	1		
White	99		
More than one race	0		
Unknown or Not Reported	2		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3		
Not Hispanic or Latino	99		
Unknown or Not Reported	4		

End points

End points reporting groups

Reporting group title	BMS 70mg
Reporting group description:	
70 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 160mg
Reporting group description:	
160 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg + Nivo 360mg
Reporting group description:	
400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg + Nivo 360mg
Reporting group description:	
1000 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met	

Primary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs)[1]
End point description:	
Number of participants with any grade adverse events (AEs). An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. Toxicities will be graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.	
End point type	Primary
End point timeframe:	
From first dose to 100 days post last dose (Up to 64 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: only summary statistics planned for this endpoint.

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants	7	6	29	35

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Participants	21	8		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Serious Adverse Events (SAEs)

End point title	Number of Participants with Serious Adverse Events (SAEs)[2]

End point description:

Number of participants with any grade serious adverse events (SAEs). A Serious Adverse Event (SAE) is any untoward medical occurrence that at any dose:
- results in death
- is life-threatening
- requires inpatient hospitalization or causes prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is an important medical event

Toxicities will be graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

End point type	Primary

End point timeframe:

From first dose to 100 days post last dose (Up to 64 months)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: only summary statistics planned for this endpoint.

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants	7	4	21	24

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Participants	11	5		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Participants with Adverse Events (AEs) Leading to

	Discontinuation[3]

End point description:

Number of participants with any grade adverse events (AEs) leading to discontinuation. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. Toxicities will be graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

End point type	Primary

End point timeframe:

From first dose to 100 days post last dose (Up to 64 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: only summary statistics planned for this endpoint.

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants	0	1	2	5

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Participants	3	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Who Died

End point title	Number of Participants Who Died[4]

End point description:

Number of participants who died due to any cause.

End point type	Primary

End point timeframe:

From first dose to 100 days post last dose (Up to 64 months)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: only summary statistics planned for this endpoint.

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants	3	2	10	16

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Participants	2	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Abnormal Hepatic Test

End point title	Number of Participants with Abnormal Hepatic Test[5]

End point description:

Number of participants with laboratory abnormalities in specific hepatic tests. The number of participants with the following laboratory abnormalities from on-treatment evaluations will be summarized:
- ALT or AST > 5xULN, > 3xULN, and > 2xULN
- Any of ALT, AST, Total Bilirubin or ALP > 8xULN
- Total bilirubin > 3xULN

ALT = Alanine Aminotransferase;
AST = Aspartate Aminotransferase;
ULN = Upper Limit of Normal

End point type	Primary

End point timeframe:

From first dose to 100 days post last dose (Up to 64 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: only summary statistics planned for this endpoint.

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants				
ALT OR AST > 5XULN	0	0	0	1
ALT OR AST > 3XULN	0	0	0	0
ALT OR AST > 2XULN	0	0	0	0
ANY OF ALT, AST, TOTAL BILIRUBIN OR ALP > 8XULN	0	0	0	1
TOTAL BILIRUBIN > 3XULN	1	0	0	0

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		

Units: Participants				
ALT OR AST > 5XULN	1	2		
ALT OR AST > 3XULN	0	0		
ALT OR AST > 2XULN	0	0		
ANY OF ALT, AST, TOTAL BILIRUBIN OR ALP > 8XULN	0	1		
TOTAL BILIRUBIN > 3XULN	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Maximum Observed Serum Concentration (Cmax)

End point title	BMS-986012 Maximum Observed Serum Concentration (Cmax)

End point description:

BMS-986012 maximum observed serum concentration (Cmax).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[6]	6[7]	28[8]	32[9]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	27.5 (± 31)	53.8 (± 28)	121 (± 26)	276 (± 37)
cycle 3 day 1 (C3D1)	33.8 (± 99999)	46.9 (± 99999)	221 (± 1)	279 (± 37)

Notes:

[6] - C1D1 N=7
C3D1 N=1
[7] - C1D1 N=6
C3D1 N=1
[8] - C1D1 N=28
C3D1 N=2
[9] - C1D1 N=32
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[10]	8[11]		
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	111 (± 33)	339 (± 25)		
cycle 3 day 1 (C3D1)	99999 (± 99999)	99999 (± 99999)		

Notes:

[10] - C1D1 N=21
C3D1 N=0
[11] - C1D1 N=8
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Area Under the Serum Concentration-time Curve from Time Zero to Time of Last Quantifiable Concentration (AUC (0-T))

End point title	BMS-986012 Area Under the Serum Concentration-time Curve from Time Zero to Time of Last Quantifiable Concentration (AUC (0-T))

End point description:

BMS-986012 area under the serum concentration-time curve from time zero to time of last quantifiable concentration (AUC (0-T)).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[12]	6[13]	28[14]	32[15]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	3997 (± 31)	5584 (± 55)	18456 (± 32)	36223 (± 40)
cycle 3 day 1 (C3D1)	7062 (± 99999)	10560 (± 99999)	42583 (± 8)	58649 (± 28)

Notes:

[12] - C1D1 N=7
C3D1 N=1
[13] - C1D1 N=6
C3D1 N=1
[14] - C1D1 N=28
C3D1 N=2
[15] - C1D1 N=32
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[16]	8[17]		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	16527 (± 31)	45126 (± 24)		
cycle 3 day 1 (C3D1)	99999 (± 99999)	99999 (± 99999)		

Notes:

[16] - C1D1 N=21
C3D1 N=0
[17] - C1D1 N=8
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Time of Maximum Observed Serum Concentration (Tmax)

End point title	BMS-986012 Time of Maximum Observed Serum Concentration (Tmax)

End point description:

BMS-986012 time of maximum observed serum concentration (Tmax).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[18]	6[19]	28[20]	32[21]
Units: hours				
median (full range (min-max))				
cycle 1 day 1 (C1D1)	2.08 (1.00 to 8.00)	2.02 (1.00 to 6.33)	2.00 (1.00 to 6.07)	1.58 (0.950 to 4.40)
cycle 3 day 1 (C3D1)	1.93 (1.93 to 1.93)	4.00 (4.00 to 4.00)	2.04 (2.02 to 2.07)	2.30 (2.05 to 4.00)

Notes:

[18] - C1D1 N=7
C3D1 N=1
[19] - C1D1 N=6
C3D1 N=1
[20] - C1D1 N=28
C3D1 N=2
[21] - C1D1 N=32
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[22]	8[23]		
Units: hours				
median (full range (min-max))				
cycle 1 day 1 (C1D1)	4.00 (1.00 to 5.40)	1.53 (1.00 to 4.30)		
cycle 3 day 1 (C3D1)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Notes:

[22] - C1D1 N=21
C3D1 N=0
[23] - C1D1 N=8
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Area Under the Serum Concentration-time Curve in One Dosing Interval AUC (TAU)

End point title	BMS-986012 Area Under the Serum Concentration-time Curve in One Dosing Interval AUC (TAU)

End point description:

BMS-986012 area under the serum concentration-time curve in one dosing interval AUC (TAU).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[24]	5[25]	26[26]	28[27]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	4300 (± 29)	8356 (± 28)	19865 (± 28)	40979 (± 34)
cycle 3 day 1 (C3D1)	7062 (± 99999)	10560 (± 99999)	42583 (± 8)	62634 (± 33)

Notes:

[24] - C1D1 N=7
C3D1 N=1
[25] - C1D1 N=5
C3D1 N=1
[26] - C1D1 N=26
C3D1 N=2
[27] - C1D1 N=28
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[28]	6[29]		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	18161 (± 30)	49031 (± 26)		
cycle 3 day 1 (C3D1)	99999 (± 99999)	99999 (± 99999)		

Notes:

[28] - C1D1 N=17
C3D1 N=0
[29] - C1D1 N=6
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Observed Serum Concentration at the End of a Dosing Interval (Ctau)

End point title	BMS-986012 Observed Serum Concentration at the End of a Dosing Interval (Ctau)

End point description:

BMS-986012 observed serum concentration at the end of a dosing interval (Ctau).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[30]	5[31]	26[32]	28[33]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	3.44 (± 38)	6.24 (± 31)	17.4 (± 32)	30.2 (± 59)
cycle 3 day 1 (C3D1)	7.39 (± 99999)	13.6 (± 99999)	42.4 (± 13)	59.2 (± 19)

Notes:

[30] - C1D1 N=7
C3D1 N=1
[31] - C1D1 N=5
C3D1 N=1
[32] - C1D1 N=26
C3D1 N=2
[33] - C1D1 N=28
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[34]	6[35]		
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	14.6 (± 44)	39.5 (± 40)		
cycle 3 day 1 (C3D1)	99999 (± 99999)	99999 (± 99999)		

Notes:

[34] - C1D1 N=17
C3D1 N=0
[35] - C1D1 N=6
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Total Body Clearance (CLT)

End point title	BMS-986012 Total Body Clearance (CLT)

End point description:

BMS-986012 total body clearance (CLT).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 1 day 1, cycle 3 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[36]	5[37]	26[38]	28[39]
Units: mL/h				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	16.3 (± 38)	19.1 (± 27)	20.1 (± 24)	24.4 (± 86)
cycle 3 day 1 (C3D1)	9.91 (± 99999)	15.2 (± 99999)	9.39 (± 8)	16.0 (± 40)

Notes:

[36] - C1D1 N=7
C3D1 N=1
[37] - C1D1 N=5
C3D1 N=1
[38] - C1D1 N=26
C3D1 N=2
[39] - C1D1 N=28
C3D1 N=3

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[40]	6[41]		
Units: mL/h				
geometric mean (geometric coefficient of variation)				
cycle 1 day 1 (C1D1)	22.0 (± 30)	20.4 (± 28)		
cycle 3 day 1 (C3D1)	99999 (± 99999)	99999 (± 99999)		

Notes:

[40] - C1D1 N=17
C3D1 N=0

[41] - C1D1 N=6
C3D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Trough Observed Serum Concentration (Ctrough)

End point title	BMS-986012 Trough Observed Serum Concentration (Ctrough)

End point description:

BMS-986012 trough observed serum concentration (Ctrough).
'99999'=NA
'N'= Number of Subjects Analyzed

End point type	Secondary

End point timeframe:

Cycle 2 day 1, cycle 3 day 1, cycle 4 day 1, cycle 7 day 1, cycle 11 day 1. cycle 15 day 1 (including pre-dose, 1, 2, 4, 8, 24, 72, 168, 336 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[42]	4[43]	22[44]	18[45]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
cycle 2 day 1 (C2D1)	4186 (± 27)	7211 (± 17)	18810 (± 29)	36990 (± 54)
cycle 3 day 1 (C3D1)	6570 (± 99999)	9100 (± 99999)	29232 (± 36)	68589 (± 57)
cycle 4 day 1 (C4D1)	7390 (± 99999)	13600 (± 99999)	35122 (± 26)	90207 (± 68)
cycle 7 day 1 (C7D1)	9040 (± 99999)	13700 (± 99999)	38315 (± 27)	107444 (± 58)
cycle 11 day 1 (C11D1)	9930 (± 99999)	99999 (± 99999)	32251 (± 14)	102980 (± 67)
cycle 15 day 1 (C15D1)	8029 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[42] - C2D1 N=4
C3D1 N=1
C4D1 N=1
C7D1 N=1
C11D1 N=1
C15D1 N=1
[43] - C2D1 N=4
C3D1 N=1
C4D1 N=1
C7D1 N=1
C11D1 N=0
C15D1 N=0
[44] - C2D1 N=22
C3D1 N=9
C4D1 N=6

C7D1 N=4
C11D1 N=2
C15D1 N=0
[45] - C2D1 N=18
C3D1 N=7
C4D1 N=5
C7D1 N=4
C11D1 N=2
C15D1 N=0

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13[46]	5[47]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
cycle 2 day 1 (C2D1)	14544 (± 84)	36391 (± 43)		
cycle 3 day 1 (C3D1)	26016 (± 37)	158801 (± 85)		
cycle 4 day 1 (C4D1)	26102 (± 63)	157000 (± 99999)		
cycle 7 day 1 (C7D1)	38405 (± 9)	99999 (± 99999)		
cycle 11 day 1 (C11D1)	34400 (± 99999)	99999 (± 99999)		
cycle 15 day 1 (C15D1)	99999 (± 99999)	99999 (± 99999)		

Notes:
[46] - C2D1 N=13
C3D1 N=7
C4D1 N=6
C7D1 N=3
C11D1 N=1
C15D1 N=0
[47] - C2D1 N=5
C3D1 N=3
C4D1 N=1
C7D1 N=0
C11D1 N=0
C15D1 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Accumulation Index (AI_AUC)

End point title	BMS-986012 Accumulation Index (AI_AUC)

End point description:

BMS-986012 accumulation index. Ratio of an exposure measure at steady state to that after the first dose.
'99999'=NA

End point type	Secondary

End point timeframe:

Cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.56 (± 99999)	1.55 (± 99999)	1.62 (± 22)	1.39 (± 51)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[48]	0[49]		
Units: Ratio				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[48] - 0 subjects analyzed

[49] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Average Concentration Over a Dosing Interval (Css-avg)

End point title	BMS-986012 Average Concentration Over a Dosing Interval (Css-avg)

End point description:

BMS-986012 Average concentration over a dosing interval ([AUC(TAU)/tau] (Css-avg).
'99999'=NA

End point type	Secondary

End point timeframe:

Cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	3
Units: ug/mL				
geometric mean (geometric coefficient of variation)	13.9 (± 99999)	22.0 (± 99999)	82.1 (± 11)	119 (± 33)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[50]	0[51]		
Units: ug/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[50] - 0 subjects analyzed

[51] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Ctau Accumulation Index (AI_Ctau)

End point title	BMS-986012 Ctau Accumulation Index (AI_Ctau)

End point description:

BMS-986012 Ctau accumulation index (AI_Ctau). Ratio of an exposure measure at steady state to that after the first dose.
'99999'=NA

End point type	Secondary

End point timeframe:

Cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.81 (± 99999)	2.31 (± 99999)	1.76 (± 0)	1.08 (± 82)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[52]	0[53]		
Units: Ratio				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[52] - 0 subjects analyzed

[53] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Cmax Accumulation Index (AI_Cmax)

End point title	BMS-986012 Cmax Accumulation Index (AI_Cmax)

End point description:

BMS-986012 Cmax accumulation index (AI_Cmax). Ratio of an exposure measure at steady state to that after the first dose.
'99999'=NA

End point type	Secondary

End point timeframe:

Cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.994 (± 99999)	1.47 (± 99999)	1.22 (± 11)	0.940 (± 70)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[54]	0[55]		
Units: Ratio				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[54] - 0 subjects analyzed

[55] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)

End point description:

BOR defined as the best response designation over the study as a whole.
Complete Response (CR) = Disappearance of all target lesions;
Partial Response (PR) = At least a 30% decrease in the sum of diameters of target lesions;
Stable Disease (SD) = Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD;
Progressive Disease (PD) = At least a 20% increase in the sum of diameters of target lesions and the sum must demonstrate an absolute increase of at least 5 mm

End point type	Secondary

End point timeframe:

From first dose to the last tumor assessment prior to subsequent therapy (Up to 97 months)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Participants				
Complete Response	1	0	0	0
Partial Response	0	0	1	1
Stable Disease	0	2	8	8
Progressive Disease	4	2	18	21
Not evaluable	2	2	2	5

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Participants				
Complete Response	1	0		
Partial Response	8	2		
Stable Disease	2	1		
Progressive Disease	9	3		
Not evaluable	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986012 Effective Elimination (T-HALFeff)

End point title	BMS-986012 Effective Elimination (T-HALFeff)

End point description:

BMS-986012 effective elimination (T-HALFeff) that explains the degree of accumulation observed for a specific exposure measure.
'99999'=NA

End point type	Secondary

End point timeframe:

Cycle 3 day 1 (including pre-dose, 1, 2, 4, and 8 hours post dose)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	1
Units: Hours				
arithmetic mean (standard deviation)	342 (± 99999)	319 (± 999999)	384 (± 154.2)	583 (± 99999)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[56]	0[57]		
Units: Hours				
arithmetic mean (standard deviation)	()	()		

Notes:

[56] - 0 subjects analyzed

[57] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)[58]

End point description:

DOR is defined as the time from first response (CR or PR) to the date of the first documented tumor progression as determined using RECIST 1.1 criteria or death due to any cause, whichever occurs first. Participants who remain alive and have not progressed will be censored on the date of their last tumor assessment.
Complete Response (CR) = Disappearance of all target lesions;
Partial Response (PR)= At least a 30% decrease in the sum of diameters of target lesions;
Progressive Disease (PD) = At least a 20% increase in the sum of diameters of target lesions and the sum must demonstrate an absolute increase of at least 5 mm

Median DOR will only be evaluated provided there are enough responding participants to warrant inclusion.

'99999'=NA

End point type	Secondary

End point timeframe:

From the date of first dose to the date of the first documented tumor progression or death due to any cause, whichever occurs first (Up to 97 months)

Notes:

[58] - 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: only pre-specified arms planned for this endpoint.

End point values	BMS 400mg + Nivo 360mg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Weeks				
median (confidence interval 95%)	114.57 (19.14 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR is defined as the percent of participants whose BOR is either CR or PR.
Complete Response (CR) = Disappearance of all target lesions;
Partial Response (PR) = At least a 30% decrease in the sum of diameters of target lesions;
Progressive Disease (PD) = At least a 20% increase in the sum of diameters of target lesions and the sum must demonstrate an absolute increase of at least 5 mm

End point type	Secondary

End point timeframe:

From first dose date to the date of first documented disease progression (Up to 97 months)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Percent of participants				
number (confidence interval 95%)	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	3.4 (0.1 to 17.8)	2.9 (0.1 to 14.9)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Percent of participants				
number (confidence interval 95%)	42.9 (21.8 to 66.0)	25.0 (3.2 to 65.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS is defined as the time from the date of first dose of study medication to the date of the first objective documentation of tumor progression or death due to any cause, if death occurred within 100 days after last BMS-986012 dose.
Progressive Disease (PD) = At least a 20% increase in the sum of diameters of target lesions and the sum must demonstrate an absolute increase of at least 5 mm

End point type	Secondary

End point timeframe:

From first dose to the date of first documented disease progression or death due to any cause, if death occurred within 100 days after last BMS-986012 dose (Up to 97 months)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	29	35
Units: Weeks				
median (confidence interval 95%)	5.50 (2.43 to 53.00)	5.86 (5.29 to 30.29)	5.79 (5.57 to 8.00)	5.36 (5.00 to 5.71)

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	8		
Units: Weeks				
median (confidence interval 95%)	17.71 (6.14 to 120.29)	5.71 (2.71 to 25.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival Rate (PFSR)

End point title	Progression Free Survival Rate (PFSR)

End point description:

PFSR is defined as the percent of participants who remain progression free and surviving at "t" weeks (t= 12, 24, 36, 48, 60, 72)
Progressive Disease (PD)=At least a 20% increase in the sum of diameters of target lesions and the sum must demonstrate an absolute increase of at least 5 mm

'N'=Number of subjects analyzed
'99999'=NA

End point type	Secondary

End point timeframe:

Weeks 12, 24, 36, 48, 60, 72

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[59]	1[60]	6[61]	7[62]
Units: Percent of participants				
number (confidence interval 95%)				
Week 12	99999 (99999 to 99999)	99999 (99999 to 99999)	21.4 (8.7 to 37.8)	20.6 (9.1 to 35.3)
Week 24	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Week 36	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Week 48	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Week 60	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Week 72	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Notes:

[59] - wk12 N=1
wk24 N=1
wk 36 N=1
wk 48 N=1
wk 60 N=0
wk 72 N=0

[60] - wk12 N=1
wk24 N=1
wk 36 N=0
wk 48 N=0
wk 60 N=0
wk 72 N=0

[61] - wk12 N=6
wk24 N=3
wk 36 N=1
wk 48 N=0
wk 60 N=0
wk 72 N=0

[62] - wk12 N=7
wk24 N=3
wk 36 N=2
wk 48 N=1
wk 60 N=1
wk 72 N=1

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11[63]	2[64]		
Units: Percent of participants				
number (confidence interval 95%)				
Week 12	55.0 (31.3 to 73.5)	99999 (99999 to 99999)		
Week 24	45.0 (23.1 to 64.7)	99999 (99999 to 99999)		
Week 36	45.0 (23.1 to 64.7)	99999 (99999 to 99999)		
Week 48	35.0 (15.7 to 55.2)	99999 (99999 to 99999)		
Week 60	35.0 (15.7 to 55.2)	99999 (99999 to 99999)		
Week 72	35.0 (15.7 to 55.2)	99999 (99999 to 99999)		

Notes:

[63] - wk12 N=11
wk24 N=9
wk 36 N=9
wk 48 N=7
wk 60 N=7
wk 72 N=6

[64] - wk12 N=2
wk24 N=2
wk 36 N=1
wk 48 N=1
wk 60 N=1
wk 72 N=0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-BMS-986012 Antibodies (ADA)

End point title	Number of Participants with Anti-BMS-986012 Antibodies (ADA)

End point description:

Number of participants with anti-BMS-986012 antibodies (ADA) with status as baseline ADA positive, ADA positive and ADA negative. Baseline ADA positive participant is a participant with baseline ADA positive sample (Day 1 predose). ADA-positive participant is a participant with at least one ADA positive sample relative to baseline at any time after initiation of treatment during the defined observation time period. ADA negative participant is a participant with no ADA positive sample after the initiation of treatment.

End point type	Secondary

End point timeframe:

From first dose to 100 days following the last BMS-986012 dose (Up to 64 months)

End point values	BMS 70mg	BMS 160mg	BMS 400mg	BMS 1000mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	27	25
Units: Participants				
Baseline ADA positive	0	0	0	1
ADA positive	0	0	0	0
ADA negative	5	5	27	25

End point values	BMS 400mg + Nivo 360mg	BMS 1000mg + Nivo 360mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	7		
Units: Participants				
Baseline ADA positive	0	0		
ADA positive	0	0		
ADA negative	14	7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and Other AEs are assessed from first dose up to 100 days post last dose (Up to 64 months). Participants were assessed for all-cause mortality from their first dose to their study completion (Up to 97 months).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	BMS 1000mg SCLC Refractory
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg SCLC Refractory
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 160mg SCLC Refractory
Reporting group description:	
160 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 70mg SCLC Refractory
Reporting group description:	
70 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg SCLC Sensitive
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg SCLC Sensitive
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 160mg SCLC Sensitive
Reporting group description:	
160 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 70mg SCLC Sensitive
Reporting group description:	
70 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg SCLC Refractory Espansion
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg SCLC Refractory Expansion
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg SCLC Sensitive Expansion
Reporting group description:	
400 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 1000mg SCLC Sensitive Expansion
Reporting group description:	
1000 mg IV BMS-986012 every 21 days until protocol-specified discontinuation criteria are met	
Reporting group title	BMS 400mg + Nivo 360mg SCLC Sensitive
Reporting group description:	
400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation	

criteria are met

Reporting group title	BMS 400mg + Nivo 360mg SCLC Refractory

Reporting group description:

400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Reporting group title	BMS 1000mg + Nivo 360mg SCLC Sensitive

Reporting group description:

1000 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Reporting group title	BMS 1000mg + Nivo 360mg SCLC Refractory

Reporting group description:

1000 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Reporting group title	BMS 400mg + Nivo 360mg SCLC Sensitive Expansion

Reporting group description:

400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Reporting group title	BMS 400mg + Nivo 360mg SCLC Refractory Expansion

Reporting group description:

400 mg IV BMS-986012 + 360 mg Nivolumab every 21 days until protocol-specified discontinuation criteria are met

Serious adverse events	BMS 1000mg SCLC Refractory	BMS 400mg SCLC Refractory	BMS 160mg SCLC Refractory
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	2 / 2 (100.00%)
number of deaths (all causes)	3	3	1
number of deaths resulting from adverse events	3	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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 disorders			

Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Superior vena cava occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (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
Respiratory, thoracic and mediastinal disorders			
Bronchial artery hypertrophy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 decompensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Radiation necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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			
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	BMS 70mg SCLC Refractory	BMS 1000mg SCLC Sensitive	BMS 400mg SCLC Sensitive
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 6 (33.33%)	4 / 4 (100.00%)
number of deaths (all causes)	3	5	3
number of deaths resulting from adverse events	1	1	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Bronchial artery hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatic failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 infectious			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Hyponatraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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	BMS 160mg SCLC Sensitive	BMS 70mg SCLC Sensitive	BMS 400mg SCLC Refractory Espansion
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	4 / 4 (100.00%)	8 / 12 (66.67%)
number of deaths (all causes)	1	4	9
number of deaths resulting from adverse events	1	2	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	2 / 4 (50.00%)	3 / 4 (75.00%)	5 / 12 (41.67%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 4
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Superior vena cava occlusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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			
Bronchial artery hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Mental status changes			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 decompensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Radiation necrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Toxicity to various agents			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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 fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			

Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Cardiac tamponade			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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 / 4 (0.00%)	1 / 4 (25.00%)	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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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

Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	0 / 4 (0.00%)	0 / 4 (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
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Acute hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hyperthyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Bacterial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	1 / 4 (25.00%)	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 / 1	0 / 0

Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	0 / 4 (0.00%)	0 / 4 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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			
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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

Serious adverse events	BMS 1000mg SCLC Refractory Expansion	BMS 400mg SCLC Sensitive Expansion	BMS 1000mg SCLC Sensitive Expansion
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	6 / 10 (60.00%)	11 / 14 (78.57%)
number of deaths (all causes)	11	9	12
number of deaths resulting from adverse events	6	3	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			

subjects affected / exposed	6 / 12 (50.00%)	3 / 10 (30.00%)	6 / 14 (42.86%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 6	0 / 3	0 / 5
Metastases to central nervous system			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (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			
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial artery hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Radiation necrosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (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
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pathological fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (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 infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (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

Serious adverse events	BMS 400mg + Nivo 360mg SCLC Sensitive	BMS 400mg + Nivo 360mg SCLC Refractory	BMS 1000mg + Nivo 360mg SCLC Sensitive
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	1 / 2 (50.00%)	2 / 5 (40.00%)
number of deaths (all causes)	6	2	5
number of deaths resulting from adverse events	3	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 2
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial artery hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pathological fracture			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS 1000mg + Nivo 360mg SCLC Refractory	BMS 400mg + Nivo 360mg SCLC Sensitive Expansion	BMS 400mg + Nivo 360mg SCLC Refractory Expansion
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 9 (44.44%)	2 / 4 (50.00%)
number of deaths (all causes)	3	4	3
number of deaths resulting from adverse events	3	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	2 / 3 (66.67%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Bronchial artery hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 decompensation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			

Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	BMS 1000mg SCLC Refractory	BMS 400mg SCLC Refractory	BMS 160mg SCLC Refractory
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Poor venous access			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Infusion site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contrast media reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Penile erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sneezing			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Body temperature fluctuation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Staphylococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post procedural urine leak			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial flutter			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dementia Alzheimer's type			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysmetria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myelosuppression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Eyelid pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Defaecation urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	4	1	1
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	1 / 2 (50.00%)
occurrences (all)	2	2	2
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Proctitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	2
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Biliary colic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	2 / 2 (100.00%)
occurrences (all)	4	4	2
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 2 (50.00%)
occurrences (all)	0	2	1
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	1	1

Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 2 (50.00%)
occurrences (all)	0	3	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 70mg SCLC Refractory	BMS 1000mg SCLC Sensitive	BMS 400mg SCLC Sensitive
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Poor venous access			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	3 / 6 (50.00%)	1 / 4 (25.00%)
occurrences (all)	2	3	1
Chills			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contrast media reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	3	2	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Delirium			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature fluctuation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcus test positive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Post procedural urine leak			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Scratch			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dysmetria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Syncope			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Myelosuppression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry eye			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	2	2
Eyelid disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Vitreous floaters			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Visual impairment			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Defaecation urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	1	1	1

Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	5	1
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Proctitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	7	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Biliary colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Onychoclasis			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Onychomadesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	2 / 3 (66.67%)	6 / 6 (100.00%)	4 / 4 (100.00%)
occurrences (all)	2	8	4
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Joint swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscle twitching			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Pain in jaw			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Escherichia pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Nail bed infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pustule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tracheitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	2	2	2
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	3
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	3 / 4 (75.00%)
occurrences (all)	1	0	3
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 160mg SCLC Sensitive	BMS 70mg SCLC Sensitive	BMS 400mg SCLC Refractory Espansion
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Poor venous access			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling cold			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	3 / 4 (75.00%)	4 / 12 (33.33%)
occurrences (all)	1	4	4
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infusion site swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nodule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contrast media reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Penile erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2

Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body temperature fluctuation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lipase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Staphylococcus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post procedural urine leak			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Dysaesthesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Dysmetria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Myoclonus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2

Myelosuppression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Eyelid disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0

Defaecation urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	3 / 4 (75.00%)	5 / 12 (41.67%)
occurrences (all)	1	3	6
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Lip blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	4 / 4 (100.00%)	2 / 12 (16.67%)
occurrences (all)	1	4	2
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Proctitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Biliary colic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Miliaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Nail hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pemphigoid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 4 (50.00%)	4 / 4 (100.00%)	12 / 12 (100.00%)
occurrences (all)	3	4	15
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash vesicular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	3 / 12 (25.00%)
occurrences (all)	1	1	3
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Muscle twitching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	6 / 12 (50.00%)
occurrences (all)	1	1	6
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	3
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hypertriglyceridaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 1000mg SCLC Refractory Expansion	BMS 400mg SCLC Sensitive Expansion	BMS 1000mg SCLC Sensitive Expansion
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	10 / 10 (100.00%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 12 (16.67%)	3 / 10 (30.00%)	0 / 14 (0.00%)
occurrences (all)	2	3	0
Poor venous access			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			

subjects affected / exposed	0 / 12 (0.00%)	2 / 10 (20.00%)	3 / 14 (21.43%)
occurrences (all)	0	3	3
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	7 / 12 (58.33%)	3 / 10 (30.00%)	12 / 14 (85.71%)
occurrences (all)	8	3	13
Chills			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Gait disturbance			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Generalised oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	4 / 12 (33.33%)	2 / 10 (20.00%)	2 / 14 (14.29%)
occurrences (all)	4	3	2
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	1	1	2
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Immune system disorders			

Dust allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Contrast media reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Acquired phimosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Penile erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	3 / 14 (21.43%)
occurrences (all)	0	1	3
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	2	1	2
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Nasal dryness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	4
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	2 / 10 (20.00%)	3 / 14 (21.43%)
occurrences (all)	0	2	3
Psychiatric disorders			
Abnormal dreams			

subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	3 / 12 (25.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	4	0	2
Delirium			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 10 (30.00%)	1 / 14 (7.14%)
occurrences (all)	1	3	1
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Body temperature fluctuation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
General physical condition abnormal			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Staphylococcus test positive			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	3 / 12 (25.00%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	3	1	2
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Infusion related reaction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Post procedural urine leak			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 12 (0.00%)	2 / 10 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	1	1	2
Atrioventricular block second degree			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Ventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cerebral ischaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Depressed level of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	2 / 10 (20.00%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hemiparesis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	3	1	1
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysmetria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Memory impairment			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Peroneal nerve palsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Parosmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Myelosuppression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Eye inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Eyelid disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Eyelids pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)	3 / 10 (30.00%)	3 / 14 (21.43%)
occurrences (all)	3	3	3
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	5 / 12 (41.67%)	2 / 10 (20.00%)	3 / 14 (21.43%)
occurrences (all)	6	2	3
Defaecation urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 12 (16.67%)	6 / 10 (60.00%)	3 / 14 (21.43%)
occurrences (all)	2	6	3
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	0	2	2
Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	7 / 12 (58.33%)	3 / 10 (30.00%)	5 / 14 (35.71%)
occurrences (all)	9	3	8
Odynophagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Proctitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	3 / 10 (30.00%)	2 / 14 (14.29%)
occurrences (all)	2	3	2

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Biliary colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Dermal cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Hyperhidrosis			
subjects affected / exposed	3 / 12 (25.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Hand dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Miliaria			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Palmar erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pemphigoid			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Rash erythematous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	2 / 10 (20.00%)	2 / 14 (14.29%)
occurrences (all)	0	2	2
Purpura			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	9 / 12 (75.00%)	8 / 10 (80.00%)	13 / 14 (92.86%)
occurrences (all)	10	9	15
Rash papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	3 / 12 (25.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Skin disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Skin discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Scab			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nocturia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Back pain			
subjects affected / exposed	4 / 12 (33.33%)	4 / 10 (40.00%)	2 / 14 (14.29%)
occurrences (all)	4	4	2
Arthritis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Muscular weakness			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	2	1	2
Musculoskeletal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Neck pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	3 / 12 (25.00%)	2 / 10 (20.00%)	1 / 14 (7.14%)
occurrences (all)	3	2	1
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pathological fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Polymyalgia rheumatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Nail bed infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Oral herpes			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pustule			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	4
Tracheitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 12 (41.67%)	7 / 10 (70.00%)	6 / 14 (42.86%)
occurrences (all)	6	7	7
Dehydration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Fluid retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	3 / 12 (25.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	4 / 12 (33.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypophagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 400mg + Nivo 360mg SCLC Sensitive	BMS 400mg + Nivo 360mg SCLC Refractory	BMS 1000mg + Nivo 360mg SCLC Sensitive
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	6 / 6 (100.00%)	2 / 2 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Poor venous access			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthenia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	1 / 2 (50.00%)	2 / 5 (40.00%)
occurrences (all)	2	1	2
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infusion site swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 6 (33.33%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Swelling face			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contrast media reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			

subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	3	0	2
Pulmonary haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Restlessness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Bacterial test positive			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Body temperature fluctuation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Staphylococcus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Post procedural urine leak			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Scratch			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Burning sensation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 6 (33.33%)	2 / 2 (100.00%)	2 / 5 (40.00%)
occurrences (all)	3	2	2
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysmetria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Peroneal nerve palsy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	4
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Syncope			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Myelosuppression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Middle ear effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eyelid disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Myopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Eyelids pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abdominal pain			

subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	3	1	1
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	2 / 5 (40.00%)
occurrences (all)	5	1	7
Defaecation urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	3	0	4
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	4
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	1 / 2 (50.00%)	3 / 5 (60.00%)
occurrences (all)	3	2	6
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	3	3	3
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Biliary colic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	3 / 5 (60.00%)
occurrences (all)	1	0	3
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Onychoclasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Onychomadesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Palmar erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Pemphigoid			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Purpura			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	5 / 6 (83.33%)	1 / 2 (50.00%)	5 / 5 (100.00%)
occurrences (all)	5	1	7
Rash papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Rash macular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Skin disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Urinary tract pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6 (33.33%)	1 / 2 (50.00%)	3 / 5 (60.00%)
occurrences (all)	2	1	3
Back pain			
subjects affected / exposed	3 / 6 (50.00%)	2 / 2 (100.00%)	2 / 5 (40.00%)
occurrences (all)	4	2	2
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	3
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	3
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	4
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tendon pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Localised infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nail bed infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pneumonia haemophilus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Pustule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Tracheitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Glucose tolerance impaired			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	2 / 5 (40.00%)
occurrences (all)	1	3	5
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 1000mg + Nivo 360mg SCLC Refractory	BMS 400mg + Nivo 360mg SCLC Sensitive Expansion	BMS 400mg + Nivo 360mg SCLC Refractory Expansion
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	9 / 9 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertension			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Poor venous access			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	4 / 9 (44.44%)	4 / 4 (100.00%)
occurrences (all)	2	4	6
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infusion site erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust allergy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Contrast media reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Penile erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pruritus genital			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Haemoptysis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Mood altered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Body temperature fluctuation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Streptococcus test positive			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Post procedural urine leak			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Burning sensation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Dysmetria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Myelosuppression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Diplopia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Swelling of eyelid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	1	6	0
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	1 / 4 (25.00%)
occurrences (all)	0	15	1
Defaecation urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	4 / 9 (44.44%)	1 / 4 (25.00%)
occurrences (all)	3	5	1
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	1	3	2
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lip blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	4 / 9 (44.44%)	2 / 4 (50.00%)
occurrences (all)	1	6	5

Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Proctitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oral discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	4 / 9 (44.44%)	1 / 4 (25.00%)
occurrences (all)	2	4	2
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Biliary colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	6	0
Dermal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 3 (33.33%)	3 / 9 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	3	2
Hyperhidrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hand dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Miliaria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Pruritus			
subjects affected / exposed	3 / 3 (100.00%)	9 / 9 (100.00%)	4 / 4 (100.00%)
occurrences (all)	3	15	4

Rash papular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	9 / 9 (100.00%)	2 / 4 (50.00%)
occurrences (all)	1	13	2
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	5	2
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Groin pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Muscle twitching			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	5	1
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Escherichia pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	2 / 4 (50.00%)
occurrences (all)	0	5	3
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pustule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	9	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Tracheitis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	1 / 9 (11.11%)	2 / 4 (50.00%)
occurrences (all)	2	2	4
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	10	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	4
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 March 2015	Schedule of activities updated.
18 December 2015	Eligibility criteria and exploratory objectives updated.
06 June 2016	Study design and drug update

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported