Clinical trial results:
A Phase I/II Multi-centre Study of AZD8931 in Combination with Weekly Paclitaxel to Assess the Safety, Tolerability, Pharmacokinetics and Efficacy in Patients with Advanced Solid Tumours and in a Selected Population with Low HER2-expressing Locally Recurrent and/or Metastatic Breast Cancer (THYME)

Summary

EudraCT number	2009-010551-26
Trial protocol	GB CZ HU SE FR IT BG BE
Global end of trial date	05 February 2015

Results information

Result version number	v1 (current)
This version publication date	23 April 2016
First version publication date	23 April 2016

Trial information

Trial identification

Sponsor protocol code	D0102C00003

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Astrazeneca
Sponsor organisation address	Macclesfield, Cheshire, United Kingdom, SK10 4TG
Public contact	Dr Serban Ghiorghiu, Astrazeneca, ClinicalTrialTransparency@astrazeneca.com
Scientific contact	Dr Serban Ghiorghiu, Astrazeneca, ClinicalTrialTransparency@astrazeneca.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	11 April 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 April 2012
Global end of trial reached?	Yes
Global end of trial date	05 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the progression free survival (PFS) in patients treated with AZD8931 in combination with weekly paclitaxel versus weekly paclitaxel alone

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 June 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	Brazil: 33
Country: Number of subjects enrolled	Bulgaria: 11
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	Czech Republic: 18
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Panama: 4
Country: Number of subjects enrolled	Peru: 25
Country: Number of subjects enrolled	Spain: 41
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	Switzerland: 3
Country: Number of subjects enrolled	United Kingdom: 21
Worldwide total number of subjects	210
EEA total number of subjects	137

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)	173
From 65 to 84 years	37
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Phase I: 20 patients enrolled, 6 to AZD8931 160mg, 2 to AZD8931 120 mg, 6 to AZD8931 80 mg and 6 to AZD8931 40mg. Phase II: 305 enrolled, 190 randomised, 94 and 96 allocated to AZD8931 40mg + Paclitaxel and Placebo + Paclitaxel respectively. Enrolled patients differs slightly from protocol as focus was on achieving number to be randomised.

Pre-assignment

Screening details:

Phase I: 20 patients enrolled, 6 to AZD8931 160mg, 2 to AZD8931 120 mg, 6 to AZD8931 80 mg and 6 to AZD8931 40mg. Phase II: 305 enrolled, 190 randomised, 94 and 96 allocated to AZD8931 40mg + Paclitaxel and Placebo + Paclitaxel respectively. Enrolled patients differs slightly from protocol as focus was on achieving number to be randomised.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

Part A not blinded. Part B blinded , 1:1 randomisation

Arms

Are arms mutually exclusive?	Yes
Arm title	AZD8931 160 mg bd

Arm description:

Part A: AZD8931 160mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle

Arm type	Experimental
Investigational medicinal product name	AZD8931
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

160mg bd

Arm title	AZD8931 120 mg bd

Arm description:

Part A: AZD8931 120mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle

Arm type	Experimental
Investigational medicinal product name	AZD8931
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

120mg bd

Arm title	AZD8931 80 mg bd

Arm description:

Part A: AZD8931 80mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day

cycle

Arm type	Experimental
Investigational medicinal product name	AZD8931
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80mg bd

Arm title	AZD8931 40 mg bd

Arm description:

Part A: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle

Arm type	Experimental
Investigational medicinal product name	AZD8931
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

40mg bd

Arm title	AZD8931 40MG bd + Paclitaxel

Arm description:

Part B: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle

Arm type	Experimental
Investigational medicinal product name	AZD8931
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

AZD8931 40mg bd

Arm title	Placebo + Paclitaxel

Arm description:

Part B: Placebo (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle

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

Dosage and administration details:

placebo to match bd

Number of subjects in period 1	AZD8931 160 mg bd	AZD8931 120 mg bd	AZD8931 80 mg bd
Started	6	2	6
Completed	0	0	0
Not completed	6	2	6
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	1
Adverse event, non-fatal	1	2	-
Condition under investigation worsened	4	-	5

Number of subjects in period 1	AZD8931 40 mg bd	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel
Started	6	94	96
Completed	0	65	70
Not completed	6	29	26
Adverse event, serious fatal	-	28	24
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	3	-	-
Condition under investigation worsened	3	-	-

Baseline characteristics

Reporting groups	
Reporting group title	AZD8931 160 mg bd
Reporting group description:	
Part A: AZD8931 160mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 120 mg bd
Reporting group description:	
Part A: AZD8931 120mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 80 mg bd
Reporting group description:	
Part A: AZD8931 80mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 40 mg bd
Reporting group description:	
Part A: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 40MG bd + Paclitaxel
Reporting group description:	
Part B: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	Placebo + Paclitaxel
Reporting group description:	
Part B: Placebo (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	

Reporting group values	AZD8931 160 mg bd	AZD8931 120 mg bd	AZD8931 80 mg bd
Number of subjects	6	2	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	1	6
From 65-84 years	1	1	0
85 years and over	0	0	0
Age Continuous | Age for Part A Units: Years			
arithmetic mean	52.7	62	47.2
standard deviation	± 11.78	± 16.97	± 5.85
Gender, Male/Female Units: Participants			
Female	5	2	5
Male	1	0	1

Age, Customized Units: Subjects			
18-<50 years	3	0	3
50-<=65 years	2	1	3
>65-<75 years	1	1	0
>=75 years	0	0	0
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	6	2	6
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	6	2	6
Native American	0	0	0
Native Alaskan / Inuit	0	0	0
Native Hawaiian / Pacific Islander	0	0	0
African	0	0	0
African-American	0	0	0
African-Caribbean	0	0	0
Asian (other than Chinese and Japanese)	0	0	0
Chinese	0	0	0
Japanese	0	0	0
Other	0	0	0
Not Applicable	0	0	0

Reporting group values	AZD8931 40 mg bd	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel
Number of subjects	6	94	96
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	72	84
From 65-84 years	1	22	12
85 years and over	0	0	0
Age Continuous | Age for Part A Units: Years			
arithmetic mean	54.8	54.5	53.1
standard deviation	± 11.07	± 11.87	± 10.64

Gender, Male/Female Units: Participants			
Female	4	94	96
Male	2	0	0
Age, Customized Units: Subjects			
18-<50 years	2	34	38
50-<=65 years	3	38	46
>65-<75 years	1	18	11
>=75 years	0	4	1
Race Units: Subjects			
American Indian or Alaska Native	0	2	2
Asian	0	0	1
Black or African American	0	4	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	6	75	74
Other	0	13	18
Ethnicity Units: Subjects			
Hispanic or Latino	6	35	31
Native American	0	0	0
Native Alaskan / Inuit	0	0	0
Native Hawaiian / Pacific Islander	0	0	0
African	0	0	0
African-American	0	0	0
African-Caribbean	0	0	1
Asian (other than Chinese and Japanese)	0	0	1
Chinese	0	0	0
Japanese	0	0	0
Other	0	47	49
Not Applicable	0	12	14

Reporting group values	Total		
Number of subjects	210		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	173		
From 65-84 years	37		
85 years and over	0		

Age Continuous | Age for Part A Units: Years arithmetic mean standard deviation	 -		
Gender, Male/Female Units: Participants			
Female	206		
Male	4		
Age, Customized Units: Subjects			
18-<50 years	80		
50-<=65 years	93		
>65-<75 years	32		
>=75 years	5		
Race Units: Subjects			
American Indian or Alaska Native	4		
Asian	1		
Black or African American	5		
Native Hawaiian or Other Pacific Islander	0		
White	169		
Other	31		
Ethnicity Units: Subjects			
Hispanic or Latino	86		
Native American	0		
Native Alaskan / Inuit	0		
Native Hawaiian / Pacific Islander	0		
African	0		
African-American	0		
African-Caribbean	1		
Asian (other than Chinese and Japanese)	1		
Chinese	0		
Japanese	0		
Other	96		
Not Applicable	26		

End points

End points reporting groups

Reporting group title	AZD8931 160 mg bd
Reporting group description:	
Part A: AZD8931 160mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 120 mg bd
Reporting group description:	
Part A: AZD8931 120mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 80 mg bd
Reporting group description:	
Part A: AZD8931 80mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 40 mg bd
Reporting group description:	
Part A: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	AZD8931 40MG bd + Paclitaxel
Reporting group description:	
Part B: AZD8931 40mg (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	
Reporting group title	Placebo + Paclitaxel
Reporting group description:	
Part B: Placebo (bd) plus weekly paclitaxel of 90mg/m2 on days 1, 8 and 15 of each 28 day cycle	

Primary: Phase I: The number of dose limiting toxicities in AZD8931 in combination with weekly paclitaxel

End point title	Phase I: The number of dose limiting toxicities in AZD8931 in combination with weekly paclitaxel[1][2]
End point description:	
DLT is an AE or laboratory abnormality related to AZD8931, starting during the DLT evaluation period and meeting any of the following criteria (further detail in protocol): Symptomatic ocular surface lesion; CTCAE grade 4 haematological AE; CTCAE grade ≥3 of febrile neutropenia / neutropenia / thrombocytopenia / hyperkalaemia / hyperglycaemia / hypotension / urological toxicity / ILD / pneumonitis; QTcF interval > 500 msec, two ECGs ≥ 30 minutes apart; Symptomatic congestive cardiac failure and a drop in LVEF; Decrease in LVEF of ≥20% to below the LLN; CS rash remaining CTCAE grade ≥3 for ≥5 days despite optimal treatment; CTCAE grade ≥3 nausea, vomiting or diarrhoea, despite optimal therapy; Other CTCAE grade ≥3 toxicity which, in the opinion of the investigator, is CS and related to AZD8931; Delay to the administration of paclitaxel on D1 of Cycle 2 by ≥7 days. Patients could have more than one DLT.	
End point type	Primary
End point timeframe:	
Weekly visits for routine safety monitoring from Day 1 to Day 28 for each participant	

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: There is no analysis for the DLT data as, as per the protocol, this data was to be used to determine the maximum tolerated dose and no analysis was documented in the protocol.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per the study protocol, the assessment of maximum tolerated dose was only to be performed for part A of the study, and so DLTs were only determined in part A. As such, data is only reported for the Part B treatment groups.

End point values	AZD8931 160 mg bd	AZD8931 120 mg bd	AZD8931 80 mg bd	AZD8931 40 mg bd
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	6	6
Units: Number of Dose Limiting Toxicities				
Total	2	1	2	0
Eye disorders: Keratitis	1	0	0	0
Eye disorders: Photophobia	1	0	0	0
Gastrointestinal disorders: Diarrhoea	1	1	0	0
Gastrointestinal disorders: Oesophagitis	0	0	1	0
Infections and infestations: Rash pustular	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Phase II: Progression-free-survival (PFS) were analyzed in patients treated with AZD8931 in combination with weekly paclitaxel versus weekly paclitaxel alone

End point title	Phase II: Progression-free-survival (PFS) were analyzed in patients treated with AZD8931 in combination with weekly paclitaxel versus weekly paclitaxel alone[3]

End point description:

Time from the date of randomization until the date of objective disease progression (as per RECIST 1.1) or the date of death (by any cause in the absence of progression)

End point type	Primary

End point timeframe:

Baseline and every 8 weeks, accessed up to data cut off on 11th April 2012

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As per the study protocol, the analysis of ORR was only to be performed for part B of the study. As such, data is only reported for the Part B treatment groups.

End point values	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	96		
Units: Months				
median (inter-quartile range (Q1-Q3))	8.7 (4.2 to 12.9)	9.1 (3.4 to 14.8)		

Statistical analyses

Statistical analysis title	PFS in AZD8931+ paclitaxel v paclitaxel alone

Statistical analysis description:

Originally, 166 patients were to be randomised to observe at least 133 progression events, based on HR=0.67, 80% power, 2-sided 5% significant level and a median of 6 months for the placebo arm. After

190 patients were randomised, the analysis was performed at an similar level of maturity (70%) as originally planned (72%), after approximately 133 events.

Comparison groups	AZD8931 40MG bd + Paclitaxel v Placebo + Paclitaxel
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.679 [4]
Method	Cox Proportional Hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.52

Notes:

[4] - Statistical significance threshold at this analysis was 5%

Secondary: Phase II: Objective tumour response rate (ORR) was compared in patients treated with AZD8931 in combination with weekly paclitaxel versus weekly paclitaxel alone

End point title	Phase II: Objective tumour response rate (ORR) was compared in patients treated with AZD8931 in combination with weekly paclitaxel versus weekly paclitaxel alone[5]

End point description:

The number of subjects with at least one visit response of CR or PR (Per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) for target lesions and assessed by MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), >=30% decrease in the sum of the longest diameter of target lesions; Progressive disease (PD), A ≥ 20% increase in the sum of diameters of target lesions and an absolute increase of ≥ 5mm; Stable disease (SD), Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD; Not Evaluable (NE), All target lesion measurements are missing or >1/3 target lesion measurements are missing and sum of diameters of non-missing target lesions does not qualify for PD; Not applicable (NA), No target lesions are recorded at baseline))

End point type	Secondary

End point timeframe:

Baseline and every 8 weeks, accessed up to data cut off on 11th April 2012

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per the study protocol, the analysis of ORR was only to be performed for part B of the study. As such, data is only reported for the Part B treatment groups.

End point values	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	85		
Units: Participants				
Total	52	35		
Complete Response	11	6		
Partial Response	41	29		

Statistical analyses

Statistical analysis title	ORR in AZD8931+ paclitaxel v paclitaxel alone

Statistical analysis description:

Originally, 166 patients were to be randomised to observe at least 133 progression events, based on HR=0.67, 80% power, 2-sided 5% significant level and a median of 6 months for the placebo arm. After 190 patients were randomised, the analysis was performed at an similar level of maturity (70%) as originally planned (72%), after approximately 133 events.

Comparison groups	AZD8931 40MG bd + Paclitaxel v Placebo + Paclitaxel
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026 [6]
Method	Logistic Regression
Parameter estimate	Odds ratio (OR)
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	3.75

Notes:

[6] - Statistical significance threshold at this analysis was 5%

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs will be collected from time of signed informed consent throughout the treatment period and including the 30-day safety follow up period after the last dose of study treatment

Adverse event reporting additional description:

In part B, SAEs considered related to study procedures should continue to be collected while patients are followed up for disease progression.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	1415

Reporting groups

Reporting group title	AZD8931 40 mg bd

Reporting group description:

NA

Reporting group title	AZD8931 80 mg bd

Reporting group description:

NA

Reporting group title	AZD8931 120 mg bd

Reporting group description:

NA

Reporting group title	AZD8931 160 mg bd

Reporting group description:

NA

Reporting group title	AZD8931 40MG bd + Paclitaxel

Reporting group description:

NA

Reporting group title	Placebo + Paclitaxel

Reporting group description:

NA

Serious adverse events	AZD8931 40 mg bd	AZD8931 80 mg bd	AZD8931 120 mg bd
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
THROMBOSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
BREAST FIBROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
HYDROTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (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
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (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
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BODY TEMPERATURE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
EJECTION FRACTION DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (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
Injury, poisoning and procedural complications			
HUMERUS FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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

PUBIS FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
CONVULSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
PANCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Eye disorders			
KERATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
DIARRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
OESOPHAGITIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	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
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 NECROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
RENAL FAILURE ACUTE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
MYOPATHY			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (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
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
PLEURAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
DEVICE RELATED SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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 PRIMARY ATYPICAL			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
PYELONEPHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
RASH PUSTULAR			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	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
SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
HYPOKALAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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	AZD8931 160 mg bd	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	24 / 94 (25.53%)	14 / 95 (14.74%)
number of deaths (all causes)	2	28	24
number of deaths resulting from adverse events			
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
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			
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
BREAST FIBROSIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
HYDROTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
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	0 / 6 (0.00%)	4 / 94 (4.26%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
Investigations			
BODY TEMPERATURE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
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			
HUMERUS FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PUBIS FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
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			
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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			
CONVULSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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

Eye disorders			
KERATITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	2 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
OESOPHAGITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN NECROSIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
SKIN ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
RENAL FAILURE ACUTE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Musculoskeletal and connective tissue disorders			
MYOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
PLEURAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DEVICE RELATED SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
PNEUMONIA PRIMARY ATYPICAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
PYELONEPHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PUSTULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
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%)	2 / 94 (2.13%)	0 / 95 (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
SEPTIC SHOCK			

subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	AZD8931 40 mg bd	AZD8931 80 mg bd	AZD8931 120 mg bd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BREAST CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UTERINE LEIOMYOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHLEBITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VASCULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	5 / 6 (83.33%)	6 / 6 (100.00%)	2 / 2 (100.00%)
occurrences (all)	8	11	2
AXILLARY PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FATIGUE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FEELING COLD			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INFUSION SITE DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUCOSAL DRYNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
NODULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
OEDEMA PERIPHERAL			

subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
SPINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
XEROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BREAST ENGORGEMENT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BREAST HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BREAST INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GENITAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GENITAL RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
VULVAL ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOPNEUMOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	3	3	0
DYSPHONIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
DYSPNOEA			

subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	5	0	1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	2	4	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPEROXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL MUCOSAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OBSTRUCTIVE AIRWAYS DISORDER			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RHINALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
THROAT IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER AIRWAY OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHEEZING			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
AFFECT LABILITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BRADYPHRENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NERVOUSNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

RESTLESSNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SLEEP DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CAPILLARY FRAGILITY TEST			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM CHANGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE			

INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PULMONARY PHYSICAL EXAMINATION ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URINE COLOUR ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

ARTHROPOD BITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD STING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEAD INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LACERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

RECALL PHENOMENON			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
THERMAL BURN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WOUND			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WOUND DEHISCENCE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
ANGINA UNSTABLE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CARDIAC FAILURE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
AGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
AMNESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANOSMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
APHONIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ATAXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
DYSAESTHESIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

DYSARTHRIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
FACIAL NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOKINESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOSMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MIGRAINE WITH AURA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MOTOR DYSFUNCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POLYNEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
NEUROTOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	4 / 6 (66.67%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Blood and lymphatic system disorders			
ANAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GRANULOCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
DEAFNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EAR DISCOMFORT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
EAR PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
VERTIGO			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VERTIGO POSITIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
ASTHENOPIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLEPHARITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATARACT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
DRY EYE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA OF EYELID			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
EXTRAOCULAR MUSCLE PARESIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
EYELID OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
KERATITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
MACULAR DEGENERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MYOPIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
OCULAR TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PUNCTATE KERATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SCLERAL HYPERAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
XEROPHTHALMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	4 / 6 (66.67%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
ANAL FISSURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

ANAL PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APHTHOUS STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
CONSTIPATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	5 / 6 (83.33%)	6 / 6 (100.00%)	2 / 2 (100.00%)
occurrences (all)	12	25	3
DRY MOUTH			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTRIC DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

GASTRIC ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INTESTINAL POLYP			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIP DRY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUCOUS STOOLS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	1 / 2 (50.00%)
occurrences (all)	1	3	1
ODYNOPHAGIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ORAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL MUCOSAL BLISTERING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERIANAL ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RECTAL FISSURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	1 / 2 (50.00%)
occurrences (all)	2	7	1
TOOTHACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Hepatobiliary disorders			
GALLBLADDER PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEPATOTOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
DERMAL CYST			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DRUG ERUPTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEAT RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INTERTRIGO			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MADAROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAIL PIGMENTATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
PRURITUS GENERALISED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PURPURA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

RASH			
subjects affected / exposed	3 / 6 (50.00%)	5 / 6 (83.33%)	1 / 2 (50.00%)
occurrences (all)	5	19	1
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH GENERALISED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PRURITIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN CHAPPED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

SKIN IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN STRIAE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
SKIN TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SWELLING FACE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TELANGIECTASIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOXIC SKIN ERUPTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DERMATOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

DRY SKIN			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
BLADDER PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PYURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE ACUTE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
ARTHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
BURSITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
JOINT SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIMB DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE CONTRACTURE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE RIGIDITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
MYALGIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PAIN IN JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SENSATION OF HEAVINESS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS INFECTIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
DERMATOPHYTOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ERYSIPELAS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

FOLLICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FURUNCLE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LUNG INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAIL BED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL PUSTULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHARYNGOTONSILLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
RHINITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TINEA PEDIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TRACHEITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
VAGINAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VULVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

INFLUENZA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SOFT TISSUE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TINEA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TONSILLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URETERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DECREASED APPETITE			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	2	3	2
FLUID RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	AZD8931 160 mg bd	AZD8931 40MG bd + Paclitaxel	Placebo + Paclitaxel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	93 / 94 (98.94%)	94 / 95 (98.95%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BREAST CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
UTERINE LEIOMYOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	2 / 95 (2.11%)
occurrences (all)	0	11	5
HAEMATOMA			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HOT FLUSH			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	3 / 95 (3.16%)
occurrences (all)	0	2	3
HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	3 / 95 (3.16%)
occurrences (all)	0	24	4
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	3 / 95 (3.16%)
occurrences (all)	0	0	3
LYMPHOEDEMA			
subjects affected / exposed	1 / 6 (16.67%)	3 / 94 (3.19%)	6 / 95 (6.32%)
occurrences (all)	1	3	6
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PHLEBITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VASCULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
VARICOSE VEIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
ASTHENIA			

subjects affected / exposed	5 / 6 (83.33%)	25 / 94 (26.60%)	12 / 95 (12.63%)
occurrences (all)	7	30	16
AXILLARY PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
CATHETER SITE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
CHILLS			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	0 / 95 (0.00%)
occurrences (all)	0	5	0
DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
FACE OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
FATIGUE			
subjects affected / exposed	0 / 6 (0.00%)	25 / 94 (26.60%)	25 / 95 (26.32%)
occurrences (all)	0	40	29
FEELING COLD			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	4	0
GAIT DISTURBANCE			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	1	1	2
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	3 / 95 (3.16%)
occurrences (all)	0	1	3
INFUSION SITE DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
IRRITABILITY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
MALAISE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
MUCOSAL DRYNESS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	21 / 94 (22.34%)	9 / 95 (9.47%)
occurrences (all)	0	35	9
NODULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	0 / 95 (0.00%)
occurrences (all)	0	5	0
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	3 / 95 (3.16%)
occurrences (all)	0	4	3
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	10 / 94 (10.64%)	11 / 95 (11.58%)
occurrences (all)	0	13	18
PAIN			

subjects affected / exposed	0 / 6 (0.00%)	9 / 94 (9.57%)	4 / 95 (4.21%)
occurrences (all)	0	16	17
PYREXIA			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	11 / 95 (11.58%)
occurrences (all)	0	9	11
SPINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
XEROSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	3 / 95 (3.16%)
occurrences (all)	0	5	4
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
BREAST ENGORGEMENT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
BREAST HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BREAST INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
BREAST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	2 / 95 (2.11%)
occurrences (all)	0	5	2
GENITAL DISCHARGE			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
GENITAL RASH			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
VAGINAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
VULVAL ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
BRONCHOPNEUMOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
COUGH			
subjects affected / exposed	2 / 6 (33.33%)	12 / 94 (12.77%)	19 / 95 (20.00%)
occurrences (all)	2	14	26
DYSPHONIA			
subjects affected / exposed	1 / 6 (16.67%)	2 / 94 (2.13%)	3 / 95 (3.16%)
occurrences (all)	1	2	3
DYSPNOEA			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	8 / 95 (8.42%)
occurrences (all)	0	10	8
DYSPNOEA EXERTIONAL			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
EPISTAXIS			
subjects affected / exposed	1 / 6 (16.67%)	19 / 94 (20.21%)	11 / 95 (11.58%)
occurrences (all)	1	21	12
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HICCUPS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HYPEROXIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
NASAL CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
NASAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
NASAL DRYNESS			
subjects affected / exposed	1 / 6 (16.67%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	1	3	0
NASAL MUCOSAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	2
NASAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
OROPHARYNGEAL DISCOMFORT			

subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	3 / 95 (3.16%)
occurrences (all)	0	2	3
PLEURITIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RHINALGIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	4	0
SINUS CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
THROAT IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
UPPER AIRWAY OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
WHEEZING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
RHINORRHOEA			

subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	1 / 95 (1.05%)
occurrences (all)	0	3	1
Psychiatric disorders			
AFFECT LABILITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
ANXIETY			
subjects affected / exposed	0 / 6 (0.00%)	6 / 94 (6.38%)	11 / 95 (11.58%)
occurrences (all)	0	6	13
APATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
BRADYPHRENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
DEPRESSED MOOD			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	4 / 95 (4.21%)
occurrences (all)	0	4	4
DEPRESSION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	4 / 95 (4.21%)
occurrences (all)	0	2	4
INSOMNIA			
subjects affected / exposed	1 / 6 (16.67%)	12 / 94 (12.77%)	14 / 95 (14.74%)
occurrences (all)	1	13	14
MOOD ALTERED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	2
NERVOUSNESS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
RESTLESSNESS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0

SLEEP DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	3 / 95 (3.16%)
occurrences (all)	0	1	3
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CAPILLARY FRAGILITY TEST			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ELECTROCARDIOGRAM CHANGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	4 / 95 (4.21%)
occurrences (all)	0	6	5
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	2 / 95 (2.11%)
occurrences (all)	0	2	2

HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
PULMONARY PHYSICAL EXAMINATION ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
URINE COLOUR ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	8 / 94 (8.51%)	3 / 95 (3.16%)
occurrences (all)	0	9	3
WEIGHT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	3 / 95 (3.16%)
occurrences (all)	0	0	3
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	4 / 95 (4.21%)
occurrences (all)	0	2	4
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0

ARTHROPOD STING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ESCHAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HEAD INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	3 / 95 (3.16%)
occurrences (all)	0	1	6
LACERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
LIMB INJURY			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	1	1	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RECALL PHENOMENON			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0

RIB FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
SKIN INJURY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
THERMAL BURN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
WOUND			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
WOUND DEHISCENCE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
ANGINA UNSTABLE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
PALPITATIONS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
LEFT VENTRICULAR DYSFUNCTION			

subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	2 / 95 (2.11%)
occurrences (all)	0	2	4
Nervous system disorders			
AGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
AMNESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
ANOSMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
APHASIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
APHONIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
ATAXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
COGNITIVE DISORDER			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	1	0	1
DIZZINESS			
subjects affected / exposed	1 / 6 (16.67%)	7 / 94 (7.45%)	7 / 95 (7.37%)
occurrences (all)	1	10	10
DYSAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
DYSARTHRIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0

DYSGEUSIA			
subjects affected / exposed	1 / 6 (16.67%)	9 / 94 (9.57%)	2 / 95 (2.11%)
occurrences (all)	1	13	2
FACIAL NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	13 / 94 (13.83%)	16 / 95 (16.84%)
occurrences (all)	0	21	18
HYPOAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	4 / 95 (4.21%)
occurrences (all)	0	3	4
HYPOGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
HYPOKINESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HYPOSMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	6 / 94 (6.38%)	4 / 95 (4.21%)
occurrences (all)	0	7	4
MIGRAINE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
MIGRAINE WITH AURA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
MOTOR DYSFUNCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	6

NEUROPATHY PERIPHERAL			
subjects affected / exposed	2 / 6 (33.33%)	28 / 94 (29.79%)	25 / 95 (26.32%)
occurrences (all)	3	34	27
PARAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	13 / 94 (13.83%)	19 / 95 (20.00%)
occurrences (all)	0	18	22
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	11 / 94 (11.70%)	11 / 95 (11.58%)
occurrences (all)	0	13	13
POLYNEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	3	1
PRESYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
SCIATICA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
NEUROTOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	10 / 95 (10.53%)
occurrences (all)	0	8	19
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	23 / 94 (24.47%)	10 / 95 (10.53%)
occurrences (all)	1	34	14
GRANULOCYTOPENIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	5 / 95 (5.26%)
occurrences (all)	0	27	7
LYMPH NODE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
LYMPHADENOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	14 / 94 (14.89%)	39 / 95 (41.05%)
occurrences (all)	0	42	86
Ear and labyrinth disorders			
DEAFNESS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
EAR DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
VERTIGO			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	3 / 95 (3.16%)
occurrences (all)	0	0	3
VERTIGO POSITIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TINNITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Eye disorders			
ASTHENOPIA			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BLEPHARITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CATARACT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CONJUNCTIVAL DISORDER			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	1 / 6 (16.67%)	7 / 94 (7.45%)	5 / 95 (5.26%)
occurrences (all)	1	7	5
DRY EYE			
subjects affected / exposed	3 / 6 (50.00%)	8 / 94 (8.51%)	3 / 95 (3.16%)
occurrences (all)	4	8	3
ERYTHEMA OF EYELID			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
EXTRAOCULAR MUSCLE PARESIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
EYE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
EYE HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
EYE IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	5 / 95 (5.26%)
occurrences (all)	0	4	5
EYE PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
EYE PRURITUS			
subjects affected / exposed	1 / 6 (16.67%)	2 / 94 (2.13%)	3 / 95 (3.16%)
occurrences (all)	1	2	3
EYELID OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
KERATITIS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	1	1	1
LACRIMATION INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	6	1
MACULAR DEGENERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
MYOPIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	3 / 95 (3.16%)
occurrences (all)	0	3	3
OCULAR TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
PHOTOPHOBIA			
subjects affected / exposed	1 / 6 (16.67%)	2 / 94 (2.13%)	2 / 95 (2.11%)
occurrences (all)	2	2	2
PUNCTATE KERATITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
SCLERAL HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VISUAL ACUITY REDUCED			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	2 / 95 (2.11%)
occurrences (all)	0	3	2
XEROPHTHALMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	3 / 95 (3.16%)
occurrences (all)	0	4	3
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 6 (16.67%)	8 / 94 (8.51%)	12 / 95 (12.63%)
occurrences (all)	1	9	17
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 6 (33.33%)	15 / 94 (15.96%)	7 / 95 (7.37%)
occurrences (all)	2	20	11
ANAL FISSURE			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	1 / 95 (1.05%)
occurrences (all)	0	3	1
ANAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ANAL PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1

APHTHOUS STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	1 / 95 (1.05%)
occurrences (all)	0	4	1
CHAPPED LIPS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CHEILITIS			
subjects affected / exposed	1 / 6 (16.67%)	5 / 94 (5.32%)	0 / 95 (0.00%)
occurrences (all)	1	8	0
CONSTIPATION			
subjects affected / exposed	2 / 6 (33.33%)	19 / 94 (20.21%)	23 / 95 (24.21%)
occurrences (all)	2	25	29
DENTAL CARIES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
DIARRHOEA			
subjects affected / exposed	5 / 6 (83.33%)	78 / 94 (82.98%)	33 / 95 (34.74%)
occurrences (all)	15	247	65
DRY MOUTH			
subjects affected / exposed	2 / 6 (33.33%)	5 / 94 (5.32%)	1 / 95 (1.05%)
occurrences (all)	2	5	1
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)	16 / 94 (17.02%)	9 / 95 (9.47%)
occurrences (all)	0	19	9
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	2 / 95 (2.11%)
occurrences (all)	0	3	2
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
GASTRIC DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
GASTRIC ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1

GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	5 / 95 (5.26%)
occurrences (all)	0	5	5
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
GINGIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
GLOSSITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
GLOSSODYNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HAEMORRHOIDS			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	3 / 95 (3.16%)
occurrences (all)	0	5	4
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
INTESTINAL POLYP			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
LIP DRY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
LIP PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
MUCOUS STOOLS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	3 / 6 (50.00%)	39 / 94 (41.49%)	30 / 95 (31.58%)
occurrences (all)	5	69	39
ODYNOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	1 / 95 (1.05%)
occurrences (all)	0	4	1
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
OESOPHAGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
ORAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
ORAL MUCOSAL BLISTERING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
ORAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ORAL TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
PERIANAL ERYTHEMA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
PROCTALGIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
RECTAL FISSURE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
STOMATITIS			
subjects affected / exposed	1 / 6 (16.67%)	20 / 94 (21.28%)	3 / 95 (3.16%)
occurrences (all)	1	26	3
TOOTHACHE			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	5 / 95 (5.26%)
occurrences (all)	0	3	8
VOMITING			
subjects affected / exposed	2 / 6 (33.33%)	24 / 94 (25.53%)	14 / 95 (14.74%)
occurrences (all)	3	43	27
Hepatobiliary disorders			
GALLBLADDER PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HEPATOTOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
ALOPECIA			
subjects affected / exposed	0 / 6 (0.00%)	45 / 94 (47.87%)	48 / 95 (50.53%)
occurrences (all)	0	45	49
DERMAL CYST			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
DERMATITIS			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 6 (0.00%)	21 / 94 (22.34%)	2 / 95 (2.11%)
occurrences (all)	0	40	2
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
DRUG ERUPTION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	1	1	0
ECZEMA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	2 / 95 (2.11%)
occurrences (all)	0	9	2
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
HEAT RASH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
INGROWING NAIL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
INTERTRIGO			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
MADAROSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	2 / 95 (2.11%)
occurrences (all)	0	4	2
NAIL DISORDER			

subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	8 / 95 (8.42%)
occurrences (all)	0	7	8
NAIL DYSTROPHY			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	3 / 95 (3.16%)
occurrences (all)	0	3	4
NAIL PIGMENTATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
ONYCHOCLASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
ONYCHOLYSIS			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	5 / 95 (5.26%)
occurrences (all)	0	4	5
ONYCHOMADESIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	0 / 95 (0.00%)
occurrences (all)	0	5	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	18 / 94 (19.15%)	6 / 95 (6.32%)
occurrences (all)	0	19	6
PRURITUS GENERALISED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
PURPURA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RASH			
subjects affected / exposed	4 / 6 (66.67%)	59 / 94 (62.77%)	20 / 95 (21.05%)
occurrences (all)	15	136	26

RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RASH GENERALISED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
RASH MACULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	0 / 95 (0.00%)
occurrences (all)	0	4	0
RASH PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
RASH PRURITIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	2
SKIN CHAPPED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
SKIN DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	4	0
SKIN FISSURES			
subjects affected / exposed	1 / 6 (16.67%)	7 / 94 (7.45%)	1 / 95 (1.05%)
occurrences (all)	1	7	1
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
SKIN IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1

SKIN LESION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
SKIN PLAQUE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
SKIN REACTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
SKIN STRIAE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
SKIN TOXICITY			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
SKIN ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
SWELLING FACE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TELANGIECTASIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
TOXIC SKIN ERUPTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
DERMATOSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	3 / 6 (50.00%)	32 / 94 (34.04%)	7 / 95 (7.37%)
occurrences (all)	3	36	7

HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Renal and urinary disorders			
BLADDER PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	10 / 94 (10.64%)	3 / 95 (3.16%)
occurrences (all)	0	13	4
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	4	0
POLLAKIURIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
PROTEINURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PYURIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
RENAL FAILURE ACUTE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
INCONTINENCE			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
LEUKOCYTURIA			
subjects affected / exposed	0 / 6 (0.00%)	5 / 94 (5.32%)	4 / 95 (4.21%)
occurrences (all)	0	6	5
Endocrine disorders			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	14 / 94 (14.89%)	19 / 95 (20.00%)
occurrences (all)	0	25	26
ARTHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	13 / 94 (13.83%)	16 / 95 (16.84%)
occurrences (all)	0	20	30
BONE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	2 / 95 (2.11%)
occurrences (all)	0	5	3
BURSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
LIMB DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
MUSCLE CONTRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
MUSCLE RIGIDITY			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 6 (16.67%)	3 / 94 (3.19%)	3 / 95 (3.16%)
occurrences (all)	1	3	5
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	8 / 94 (8.51%)	7 / 95 (7.37%)
occurrences (all)	0	9	7
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	6 / 94 (6.38%)	11 / 95 (11.58%)
occurrences (all)	0	9	14
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	6 / 94 (6.38%)	9 / 95 (9.47%)
occurrences (all)	0	6	9
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	3 / 95 (3.16%)
occurrences (all)	0	0	4
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	12 / 94 (12.77%)	16 / 95 (16.84%)
occurrences (all)	0	19	25
PAIN IN JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
SENSATION OF HEAVINESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
Infections and infestations			

ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	4 / 95 (4.21%)
occurrences (all)	0	1	4
CONJUNCTIVITIS BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CONJUNCTIVITIS INFECTIVE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
CYSTITIS			
subjects affected / exposed	0 / 6 (0.00%)	9 / 94 (9.57%)	3 / 95 (3.16%)
occurrences (all)	0	11	3
DERMATOPHYTOSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
DEVICE RELATED SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
EAR INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ERYSIPELAS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
FOLLICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1

FURUNCLE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	4
HERPES ZOSTER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
HORDEOLUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
LARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
LOCALISED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	4	1
LUNG INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
NAIL BED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	9 / 95 (9.47%)
occurrences (all)	0	8	12
ONYCHOMYCOSIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	2	2
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
ORAL PUSTULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
PARONYCHIA			
subjects affected / exposed	0 / 6 (0.00%)	24 / 94 (25.53%)	5 / 95 (5.26%)
occurrences (all)	0	30	6
PHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
PHARYNGOTONSILLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
RASH PUSTULAR			
subjects affected / exposed	1 / 6 (16.67%)	14 / 94 (14.89%)	2 / 95 (2.11%)
occurrences (all)	1	18	2
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	6 / 95 (6.32%)
occurrences (all)	0	4	9
RHINITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	3 / 95 (3.16%)
occurrences (all)	0	1	3
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
SINUSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	5 / 95 (5.26%)
occurrences (all)	0	0	6
SKIN INFECTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TINEA PEDIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TOOTH INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
TRACHEITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	11 / 94 (11.70%)	11 / 95 (11.58%)
occurrences (all)	0	11	13
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	19 / 94 (20.21%)	13 / 95 (13.68%)
occurrences (all)	0	29	22
VAGINAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	2 / 95 (2.11%)
occurrences (all)	0	1	2
VIRAL INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	1	2	0
VULVITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
INFLUENZA			
subjects affected / exposed	0 / 6 (0.00%)	4 / 94 (4.26%)	2 / 95 (2.11%)
occurrences (all)	0	4	2

SOFT TISSUE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
TINEA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
TONSILLITIS			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	0 / 95 (0.00%)
occurrences (all)	0	3	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
URETERITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	5 / 95 (5.26%)
occurrences (all)	0	9	13
HYPERKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 94 (3.19%)	2 / 95 (2.11%)
occurrences (all)	0	11	2
HYPOGLYCAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	7 / 94 (7.45%)	5 / 95 (5.26%)
occurrences (all)	0	8	6
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	0	2	0
DECREASED APPETITE			
subjects affected / exposed	2 / 6 (33.33%)	21 / 94 (22.34%)	15 / 95 (15.79%)
occurrences (all)	3	27	17
FLUID RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The endpoint of MTD is not statistically analysed The planned analyses of OS and PFS at 50% OS maturity were not performed AEs were coded using MedDRA v14.0 (A) and v15.0 (B) OS data was not mature enough to determine median in either group

Notes: