Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Subcutaneous LY2127399 in Patients with Systemic Lupus Erythematosus (SLE)

Summary

EudraCT number	2010-022100-42
Trial protocol	HU LV GB ES
Global end of trial date	31 March 2015

Results information

Result version number	v1 (current)
This version publication date	09 April 2018
First version publication date	09 April 2018

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDT

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01205438
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number : 13653

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	31 March 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this SLE study is to evaluate the efficacy, safety and tolerability of two different doses of LY2127399 administered in addition to standard of care therapy in participants with active SLE.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2011
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	Ecuador: 49
Country: Number of subjects enrolled	Russian Federation: 43
Country: Number of subjects enrolled	Romania: 30
Country: Number of subjects enrolled	Hungary: 53
Country: Number of subjects enrolled	United States: 428
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	Malaysia: 7
Country: Number of subjects enrolled	India: 40
Country: Number of subjects enrolled	Spain: 30
Country: Number of subjects enrolled	New Zealand: 8
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	Latvia: 9
Country: Number of subjects enrolled	Taiwan: 50
Country: Number of subjects enrolled	Brazil: 70
Country: Number of subjects enrolled	Mexico: 64
Country: Number of subjects enrolled	South Africa: 38
Country: Number of subjects enrolled	Israel: 28
Country: Number of subjects enrolled	Serbia: 76
Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	France: 4

Country: Number of subjects enrolled	Tunisia: 61
Worldwide total number of subjects	1124
EEA total number of subjects	135

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)	1091
From 65 to 84 years	33
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Entered

Pre-assignment

Screening details:

No Text Entered

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	LY2127399 every 2 weeks

Arm description:

120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Arm type	Experimental
Investigational medicinal product name	LY2127399
Investigational medicinal product code	
Other name	Tabalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Arm title	LY2127399 every 4 weeks

Arm description:

During the Treatment Period, for blinding purposes, participants will alternate injections of LY2127399 and injections of placebo every 2 weeks.

120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	LY2127399
Investigational medicinal product code	
Other name	Tabalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Subcutaneous use

Dosage and administration details:

Administered via subcutaneous injection for 52 weeks.

Arm title	Placebo

Arm description:

Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will be administered at the first dose.

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

Dosage and administration details:

Administered via subcutaneous injection for 52 weeks. A matching loading dose will be administered at the first dose.

Number of subjects in period 1	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo
Started	372	376	376
Received At Least One Dose of Study Drug	371	374	376
Participated in Follow Up	72 [1]	78 [2]	66 [3]
Completed	295	289	288
Not completed	77	87	88
Adverse event, serious fatal	1	1	3
Consent withdrawn by subject	19	25	19
Physician decision	-	3	2
Adverse event, non-fatal	19	17	24
Sponsor Decision	-	1	1
Lost to follow-up	6	7	8
Entry Criteria Not Met	16	15	13
Lack of efficacy	14	11	14
Protocol deviation	2	7	4

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 372 subjects started this arm and 371 received at least one dose of study drug. 72 participated in follow up.
[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 376 subjects started this arm and 374 received at least one dose of study drug. 78 participated in follow up.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 376 subjects started this arm and also received at least one dose of study drug. 66 participated in follow up.

Baseline characteristics

Reporting groups	
Reporting group title	LY2127399 every 2 weeks
Reporting group description:	
120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.	
Reporting group title	LY2127399 every 4 weeks
Reporting group description:	
During the Treatment Period, for blinding purposes, participants will alternate injections of LY2127399 and injections of placebo every 2 weeks. 120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug. Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.	
Reporting group title	Placebo
Reporting group description:	
Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will be administered at the first dose.	

Reporting group values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo
Number of subjects	372	376	376
Age categorical Units: Subjects			
Gender, Male/Female Units:			
Female	342	346	349
Male	30	30	27
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	110	92	99
Not Hispanic or Latino	229	233	235
Unknown or Not Reported	33	51	42
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	31	33	30
Asian	38	34	40
Native Hawaiian or Other Pacific Islander	1	2	0
Black or African American	43	46	51
White	245	247	249
More than one race	14	14	6
Unknown or Not Reported	0	0	0
At Least One BILAG A or Two BILAG B Disease Activity Scores			
The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains. BILAG score is assessed for each of the 9 organ domains using BILAG2004 index score rules; A is a severe score and B is a moderate score. The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group because not all participants will have at least one BILAG A or Two BILAG			

B Disease Activity scores.			
Units: Subjects			
At Least 1 BILAG A or 2 BILAG B Disease Activity	230	218	209
Less than 1 BILAG A or 2 BILAG B Disease Activity	142	158	167
Anti-dsDNA Antibody Level			
Units: International Unit / Milliliter (IU/mL)			
arithmetic mean	116.8	110.6	112
standard deviation	± 118.17	± 113.51	± 116.6
Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI) Score			
SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare.			
Units: units on a scale			
arithmetic mean	10.4	10.4	9.8
standard deviation	± 4.07	± 4.17	± 3.28
SLE Disease Activity Index 2000 (SLEDAI 2K) Score			
SLEDAI-2K is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.			
Units: units on a scale			
arithmetic mean	10.3	10.4	9.8
standard deviation	± 4.17	± 4.01	± 3.36
Physician's Global Assessment (PGA) Score			
PGA is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity.			
Units: units on a scale			
arithmetic mean	47.2	46.8	44.9
standard deviation	± 15.45	± 15.6	± 16.57
Time of Onset of Lupus			
Units: years			
arithmetic mean	8.36	7.94	7.74
standard deviation	± 8.5	± 7.615	± 7.078
Brief Fatigue Inventory (BFI) Score			
BFI is a participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine).			
Units: units on a scale			
arithmetic mean	5.8	5.6	5.6
standard deviation	± 2.57	± 2.81	± 2.81

Reporting group values	Total		
Number of subjects	1124		
Age categorical			
Units: Subjects			

Gender, Male/Female			
Units:			
Female	1037		
Male	87		

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	301		
Not Hispanic or Latino	697		
Unknown or Not Reported	126		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	94		
Asian	112		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	140		
White	741		
More than one race	34		
Unknown or Not Reported	0		
At Least One BILAG A or Two BILAG B Disease Activity Scores			
The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains. BILAG score is assessed for each of the 9 organ domains using BILAG2004 index score rules; A is a severe score and B is a moderate score. The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group because not all participants will have at least one BILAG A or Two BILAG B Disease Activity scores.			
Units: Subjects			
At Least 1 BILAG A or 2 BILAG B Disease Activity	657		
Less than 1 BILAG A or 2 BILAG B Disease Activity	467		
Anti-dsDNA Antibody Level Units: International Unit / Milliliter (IU/mL) arithmetic mean standard deviation	- -		
Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI) Score			
SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare.			
Units: units on a scale arithmetic mean standard deviation	- -		
SLE Disease Activity Index 2000 (SLEDAI 2K) Score			
SLEDAI-2K is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.			
Units: units on a scale arithmetic mean standard deviation	- -		
Physician's Global Assessment (PGA) Score			
PGA is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity.			
Units: units on a scale arithmetic mean standard deviation	- -		

Time of Onset of Lupus Units: years arithmetic mean standard deviation	- 		
Brief Fatigue Inventory (BFI) Score			
BFI is a participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine).			
Units: units on a scale arithmetic mean standard deviation	- 		

End points

End points reporting groups

Reporting group title	LY2127399 every 2 weeks

Reporting group description:

120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Reporting group title	LY2127399 every 4 weeks

Reporting group description:

During the Treatment Period, for blinding purposes, participants will alternate injections of LY2127399 and injections of placebo every 2 weeks.

120mg LY2127399 administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.

Reporting group title	Placebo

Reporting group description:

Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will be administered at the first dose.

Primary: Percentage of Participants Achieving an SLE Responder Index Response at Week 52

End point title	Percentage of Participants Achieving an SLE Responder Index Response at Week 52

End point description:

Percentage of participants with a ≥ 5 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A organ domain score or 2 new BILAG B organ domain scores compared with baseline.

SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). BILAG uses a single score for each of the 9 organ domains; range is from severe (A) to no disease (E). Participants who were unable to comply with allowed concomitant medications requirements were considered non-responders, as were participants who dropped out or were missing Week 52 data.

Analysis Population Description: Intention to treat (ITT), all randomized participants who received at least one dose of study drug.Non-responder imputation (NRI) included.

End point type	Primary

End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: percentage of participants				
number (not applicable)	38.5	34.8	27.7	

Statistical analyses

Statistical analysis title	Statistical Analysis: LY2127399 every 2 weeks
Comparison groups	LY2127399 every 2 weeks v Placebo
Number of subjects included in analysis	748
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Regression, Logistic

Secondary: Percentage of Participants Able to Decrease Dose of Prednisone or Equivalent With No Increase in Disease Activity at Week 52

End point title	Percentage of Participants Able to Decrease Dose of Prednisone or Equivalent With No Increase in Disease Activity at Week 52

End point description:

A participant achieves corticosteroid sparing effects if they have met the following criteria during Weeks 24 through 52; able to decrease their dose of prednisone or equivalent to 7.5 mg/day or less, have quiescent disease (BILAG C score or better in all nine systems), and no BILAG A or B flares in the previous three months, without an increase in either antimalarials or immunosuppressants on or prior to the visit.

Analysis Population Description: Intention to treat (ITT), only participants receiving a prednisone or equivalent dose of more than 7.5 mg/day at baseline are included.

End point type	Secondary

End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	129	131	
Units: percentage of participants				
number (not applicable)	21.2	14.7	11.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks in Anti-double Stranded Deoxyribonucleic Acid (Anti-dsDNA) Level

End point title	Change From Baseline to 52 Weeks in Anti-double Stranded Deoxyribonucleic Acid (Anti-dsDNA) Level

End point description:

Anti-double stranded deoxyribonucleic acid (anti-dsDNA) is a lab analyte used to assist in the diagnosis of SLE.

Analysis Population Description: Intention to treat (ITT), Last observation carried (LOCF). LOCF endpoint is defined as the latest post-baseline response obtained on or prior to the date of Week 52 or the date of early discontinuation from the treatment period.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	368	372	372	
Units: International Units (IU)				
arithmetic mean (standard deviation)	-27.7 (± 65.31)	-26.4 (± 64.13)	-7 (± 56.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 week endpoint in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI2K) score

End point title	Change from baseline to 52 week endpoint in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI2K) score

End point description:

SLE Disease Activity Index 2000 (SLEDAI-2K) score is a weighted, cumulative index of lupus disease activity. SLEDAI-2K is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.

Analysis Population Description: Intention to treat (ITT), Last observation carried (LOCF). LOCF endpoint is defined as the latest post-baseline response obtained on or prior to the date of Week 52 or the date of early discontinuation from the treatment period.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	368	367	372	
Units: units on a scale				
arithmetic mean (standard deviation)	-4.9 (± 4.57)	-4.7 (± 4.62)	-3.6 (± 4.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Severe SLE Flare (SFI)

End point title	Time to First Severe SLE Flare (SFI)

End point description:

The SFI uses the SELENA-SLEDAI disease activity index score, disease activity scenarios, treatment changes, and PGA to define mild/moderate and severe flares. The index takes into account the absolute change in total scores, new or worsening symptoms, and increases in corticosteroid use or hospitalization due to the disease activity.

Time to first severe SLE flare (SFI) (in days) is calculated as: (Start date of first severe SLE flare (SFI) - Date of randomization + 1).

Analysis Population Description: Zero participants analyzed. Due to program termination, analyses were not completed.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[1]	0[2]	0[3]	
Units: units on a scale				
number (not applicable)				

Notes:

[1] - Zero participants analyzed. Due to program termination, analyses were not completed.

[2] - Zero participants analyzed. Due to program termination, analyses were not completed.

[3] - Zero participants analyzed. Due to program termination, analyses were not completed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Week Endpoint in Physician's Global Assessment (PGA)

End point title	Change From Baseline to 52 Week Endpoint in Physician's Global Assessment (PGA)

End point description:

PGA is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity.

Analysis Population Description: Intention to treat (ITT), Last observation carried (LOCF). LOCF endpoint is defined as the latest post-baseline response obtained on or prior to the date of Week 52 or the date of

early discontinuation from the treatment period.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: units on a scale				
arithmetic mean (standard deviation)	-21.2 (± 21.28)	-19.2 (± 23.13)	-15.1 (± 23.52)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 week endpoint Lupus Quality of Life (LupusQOL) composite and domain scores

End point title	Change from baseline to 52 week endpoint Lupus Quality of Life (LupusQOL) composite and domain scores

End point description:

The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health (8 items), emotional health (6 items), body image (5 items), pain (3 items), planning (3 items), fatigue (4 items), intimate relationships (2 items), and burden to others (3 items). Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never".

Analysis Population Description: Intention to treat (ITT), all randomized participants who received at least one dose of study drug.Non-responder imputation (NRI) included.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: units on a scale				
arithmetic mean (standard deviation)				
Physical Health (n= 143, 131, 104)	69 (± 26.42)	66.2 (± 28.01)	70.7 (± 27.78)	
Emotional Health (n= 143, 131, 104)	72.7 (± 27.03)	72.3 (± 27.72)	74 (± 28.85)	
Body Image (n=139, 128, 97)	73.6 (± 27.79)	72.8 (± 27.6)	73.1 (± 29.76)	
Pain (n=143, 131, 104)	68.5 (± 28.98)	67.5 (± 29.78)	71.4 (± 29.8)	
Planning (n=143, 131, 104)	71 (± 30.04)	70.7 (± 31.71)	73.2 (± 33.39)	
Fatigue (n= 143, 131, 104)	65.5 (± 26.23)	62.4 (± 28.17)	69.3 (± 26.27)	

Intimate Relationships (n=132, 118, 95)	68.4 (± 33.39)	66.1 (± 33.81)	72.4 (± 31.42)	
Burden to Others (n=143, 131, 104)	62.6 (± 32.89)	63.7 (± 31.06)	69.2 (± 31.33)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 week endpoint in Brief Fatigue Inventory (BFI) scores

End point title	Change from baseline to 52 week endpoint in Brief Fatigue Inventory (BFI) scores

End point description:

A participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine).

Analysis Population Description: Intention to treat (ITT), Last observation carried (LOCF). LOCF endpoint is defined as the latest post-baseline response obtained on or prior to the date of Week 52 or the date of early discontinuation from the treatment period.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	358	352	354	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.7 (± 3.09)	-0.5 (± 2.91)	-0.5 (± 2.95)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With No Worsening in Physician Global Assessment (PGA) Score at 52 Weeks

End point title	Percentage of Participants With No Worsening in Physician Global Assessment (PGA) Score at 52 Weeks

End point description:

Physician's Global Assessment (PGA) is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-mm visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity. Scores are presented from 0 to 100.

Analysis Population Description: Intention to treat (ITT), all randomized participants who received at least one dose of study drug. Non-responder imputation (NRI) included.

End point type	Secondary

End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: percentage of participants				
number (not applicable)	32.8	37.8	42.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First New British Isles Lupus Assessment Group (BILAG A) or 2 New BILAG B SLE Flares

End point title	Time to First New British Isles Lupus Assessment Group (BILAG A) or 2 New BILAG B SLE Flares

End point description:

The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains. BILAG flare is assessed for each of the 9 organ domains using BILAG2004 index flare rules; A is a severe flare and B is a moderate flare.

Time to first BILAG A or two BILAG B flares (in days) is calculated as: (Start date of first BILAG A or two BILAG B flares - Date of randomization + 1). The two BILAG B flares must occur in different domains at the same visit.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[4]	0[5]	0[6]	
Units: days				
number (not applicable)				

Notes:

[4] - Zero participants analyzed. Due to program termination, analyses were not completed.

[5] - Zero participants analyzed. Due to program termination, analyses were not completed.

[6] - Zero participants analyzed. Due to program termination, analyses were not completed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With an Increase in Corticosteroids Dose at 52 Weeks

End point title	Percentage of Participants With an Increase in Corticosteroids Dose at 52 Weeks

End point description:

An increase in corticosteroids at a visit was defined as a change from baseline greater than 2.5 mg/day in dose or prednisone or equivalent using average daily dose of corticosteroids taken since the previous scheduled visit.

Analysis Population Description: Intention to treat (ITT), only participants receiving a prednisone or equivalent dose of more than 2.5 mg/day at baseline are included.

End point type	Secondary

End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295	289	288	
Units: percentage of participants				
number (not applicable)	4.7	6.2	5.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks Endpoint in SELENA-SLEDAI Disease Activity Score

End point title	Change From Baseline to 52 Weeks Endpoint in SELENA-SLEDAI Disease Activity Score

End point description:

Safety of Estrogens in Lupus Erythematosus National Assessment - SLE Disease Activity Index (SELENA-SLEDAI) score is a weighted, cumulative index of lupus disease activity. SELENA-SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.

Analysis Population Description: Intention to treat (ITT), Last observation carried (LOCF). LOCF endpoint is defined as the latest post-baseline response obtained on or prior to the date of Week 52 or the date of early discontinuation from the treatment period.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	368	367	372	
Units: units on a scale				
arithmetic mean (standard deviation)	-5.1 (± 4.62)	-4.8 (± 4.69)	-3.7 (± 4.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with No New BILAG A and No More Than One New BILAG B Disease Activity Scores Compared to Baseline

End point title	Number of Participants with No New BILAG A and No More Than One New BILAG B Disease Activity Scores Compared to Baseline

End point description:

The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains. BILAG flare is assessed for each of the 9 organ domains using BILAG2004 index flare rules; A is a severe flare and B is a moderate flare.

Analysis Population Description: Intention to treat (ITT), all randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: participants				
number (not applicable)	134	144	160	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Response as Measured by Modified SRI With No BILAG A or No More Than 1 BILAG B Organ Domain Flares at 52 Weeks

End point title	Percentage of Participants Achieving a Response as Measured by Modified SRI With No BILAG A or No More Than 1 BILAG B Organ Domain Flares at 52 Weeks

End point description:

Percentage of participants with a ≥ 5 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A or no more than 1 new BILAG B organ domain flare compared with baseline.

SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). BILAG flare is assessed for each of the 9 organ domains; A

is a severe flare and B is a moderate flare. Participants who were unable to comply with allowed concomitant medications requirements were considered non-responders, as were participants who dropped out or were missing Week 52 data.

Analysis Population Description: ITT, all randomized participants who received at least one dose of study drug. Non-responder imputation (NRI) included.

End point type	Secondary

End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 weeks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	372	376	376	
Units: percentage of participants				
number (not applicable)	38.7	34.8	27.7	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
H9B-MC-BCDT	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	LY2127399 Every 2 Weeks Treatment Period
Reporting group description: -	
Reporting group title	LY2127399 Every 4 Weeks Treatment Period
Reporting group description: -	
Reporting group title	Placebo Treatment Period
Reporting group description: -	
Reporting group title	LY2127399 Every 2 Weeks Follow-up Period
Reporting group description: -	
Reporting group title	LY2127399 Every 4 Weeks Follow-up Period
Reporting group description: -	
Reporting group title	Placebo Follow-up Period
Reporting group description: -	

Serious adverse events	LY2127399 Every 2 Weeks Treatment Period	LY2127399 Every 4 Weeks Treatment Period	Placebo Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 371 (12.40%)	59 / 374 (15.78%)	70 / 376 (18.62%)
number of deaths (all causes)	1	2	3
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung adenocarcinoma			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
papillary thyroid cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
squamous cell carcinoma of the vagina			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[1]	0 / 341 (0.00%)	1 / 344 (0.29%)	0 / 349 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[2]	0 / 341 (0.00%)	0 / 344 (0.00%)	2 / 349 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
accelerated hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
deep vein thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	3 / 374 (0.80%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery occlusion			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
peripheral artery aneurysm			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
raynaud's phenomenon			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
female sterilisation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[3]	1 / 341 (0.29%)	0 / 344 (0.00%)	0 / 349 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[4]	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest discomfort			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
serositis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[5]	0 / 341 (0.00%)	0 / 344 (0.00%)	1 / 349 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometrial hyperplasia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[6]	1 / 341 (0.29%)	0 / 344 (0.00%)	0 / 349 (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
menometrorrhagia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[7]	0 / 341 (0.00%)	0 / 344 (0.00%)	1 / 349 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
menorrhagia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[8]	0 / 341 (0.00%)	0 / 344 (0.00%)	1 / 349 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst ruptured			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[9]	1 / 341 (0.29%)	0 / 344 (0.00%)	0 / 349 (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
uterine haemorrhage			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[10]	1 / 341 (0.29%)	0 / 344 (0.00%)	0 / 349 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
interstitial lung disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus pneumonitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	0 / 376 (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
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleurisy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleuritic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary arterial hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	2 / 374 (0.53%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pulmonary hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
shrinking lung syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
anxiety disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
bipolar disorder			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
borderline personality disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
completed suicide			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dysthymic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
hallucination			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
intentional self-injury			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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

major depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	0 / 376 (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
neurosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
panic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
psychotic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
substance-induced psychotic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	0 / 376 (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
suicide attempt			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	0 / 376 (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
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
animal bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
femur fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal injury			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
hip fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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

multiple injuries			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
overdose			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stab wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
acute myocardial infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bradycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
cardiac failure congestive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiopulmonary failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	4 / 376 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
myocardial infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	0 / 376 (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
pericardial effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
brain oedema			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
cerebral infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
haemorrhage intracranial			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
hypoaesthesia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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

lacunar infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nervous system disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis cerebral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
disseminated intravascular coagulation			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemolytic anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
immune thrombocytopenic purpura			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
iron deficiency anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
leukocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

thrombocytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo positional			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
Eye disorders			
accommodation disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
duodenitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
food poisoning			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis erosive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
haematochezia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
haemorrhoids			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
proctitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
rectal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retroperitoneal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal perforation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
cholangitis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
cholecystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
cholecystitis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus hepatitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
Skin and subcutaneous tissue disorders			
butterfly rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cutaneous vasculitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydronephrosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	0 / 374 (0.00%)	0 / 376 (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
lupus nephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	2 / 374 (0.53%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephropathy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
nephrotic syndrome			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstructive uropathy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
proteinuria			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
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 failure acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal mass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urethral polyp			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
addison's disease			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
bursitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibromyalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
lumbar spinal stenosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	0 / 374 (0.00%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
spondylolisthesis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
systemic lupus erythematosus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 371 (0.81%)	4 / 374 (1.07%)	6 / 376 (1.60%)
occurrences causally related to treatment / all	0 / 3	0 / 4	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
atypical pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchopneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

clostridium difficile colitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 371 (0.54%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endocarditis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
epstein-barr virus infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
erysipelas alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	1 / 374 (0.27%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis salmonella			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
herpes simplex			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lobar pneumonia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
ophthalmic herpes zoster alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media acute alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perinephric abscess alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
perirectal abscess alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 371 (1.08%)	2 / 374 (0.53%)	7 / 376 (1.86%)
occurrences causally related to treatment / all	1 / 4	1 / 2	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia haemophilus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
pneumonia pneumococcal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
post procedural infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
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 tuberculosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
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 acute alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
salmonella bacteraemia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis syndrome alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
septic arthritis staphylococcal alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
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 alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
sinusitis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	2 / 374 (0.53%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal skin infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tracheobronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	2 / 374 (0.53%)	2 / 376 (0.53%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 371 (0.00%)	1 / 374 (0.27%)	0 / 376 (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
hypoglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	0 / 374 (0.00%)	0 / 376 (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
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 371 (0.00%)	0 / 374 (0.00%)	1 / 376 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LY2127399 Every 2 Weeks Follow-up Period	LY2127399 Every 4 Weeks Follow-up Period	Placebo Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 72 (11.11%)	12 / 78 (15.38%)	14 / 66 (21.21%)
number of deaths (all causes)	0	4	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung adenocarcinoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of the vagina			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[1]	0 / 67 (0.00%)	1 / 74 (1.35%)	0 / 63 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[2]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
accelerated hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery occlusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery aneurysm			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
raynaud's phenomenon			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
female sterilisation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[3]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[4]	0 / 67 (0.00%)	0 / 74 (0.00%)	1 / 63 (1.59%)
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			
asthenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest discomfort			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
serositis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[5]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometrial hyperplasia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[6]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
menometrorrhagia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[7]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
menorrhagia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[8]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst ruptured			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[9]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[10]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
acute respiratory failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus pneumonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleurisy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
pleuritic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pneumothorax			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 arterial hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shrinking lung syndrome			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
anxiety disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
borderline personality disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
completed suicide			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
depression			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
dysthymic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hallucination			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional self-injury			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neurosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
panic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

psychotic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
substance-induced psychotic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
suicide attempt			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
haemoglobin decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
accident			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
animal bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal injury			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
overdose			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
road traffic accident			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

stab wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bradycardia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 failure congestive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiopulmonary failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

pericardial effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
brain oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhage intracranial			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoaesthesia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lacunar infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nervous system disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

transient ischaemic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis cerebral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
disseminated intravascular coagulation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemolytic anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
immune thrombocytopenic purpura			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ear and labyrinth disorders			
vertigo positional			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
accommodation disorder			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
food poisoning			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis erosive			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
proctitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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

retroperitoneal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal perforation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholangitis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus hepatitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
butterfly rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cutaneous vasculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
calculus urinary			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
glomerulonephritis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydronephrosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
lupus nephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephropathy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrotic syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstructive uropathy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
proteinuria			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

renal failure acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal mass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urethral polyp			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
addison's disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibromyalgia			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
lumbar spinal stenosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
systemic lupus erythematosus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atypical pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchopneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
clostridium difficile colitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

endocarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epstein-barr virus infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis salmonella			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lobar pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ophthalmic herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
otitis media acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perinephric abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
perirectal abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia haemophilus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 mycoplasmal			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 pneumococcal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary tuberculosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
salmonella bacteraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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 arthritis staphylococcal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
septic shock			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (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
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal skin infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tracheobronchitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (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
wound infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
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			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	LY2127399 Every 2 Weeks Treatment Period	LY2127399 Every 4 Weeks Treatment Period	Placebo Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	253 / 371 (68.19%)	243 / 374 (64.97%)	251 / 376 (66.76%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	17 / 371 (4.58%)	8 / 374 (2.14%)	16 / 376 (4.26%)
occurrences (all)	17	10	16
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[11]	3 / 341 (0.88%)	2 / 344 (0.58%)	4 / 349 (1.15%)
occurrences (all)	3	2	4
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	2 / 374 (0.53%)	3 / 376 (0.80%)
occurrences (all)	9	3	4
chest pain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 371 (0.27%)	3 / 374 (0.80%)	3 / 376 (0.80%)
occurrences (all)	1	3	5
fatigue			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 371 (2.96%)	5 / 374 (1.34%)	12 / 376 (3.19%)
occurrences (all)	18	7	18
injection site erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	13 / 371 (3.50%)	6 / 374 (1.60%)	4 / 376 (1.06%)
occurrences (all)	16	13	8
injection site pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	5 / 374 (1.34%)	5 / 376 (1.33%)
occurrences (all)	11	14	14
injection site reaction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	13 / 374 (3.48%)	4 / 376 (1.06%)
occurrences (all)	35	20	4
oedema peripheral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	6 / 374 (1.60%)	7 / 376 (1.86%)
occurrences (all)	7	6	8
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	9 / 374 (2.41%)	8 / 376 (2.13%)
occurrences (all)	9	11	10
Reproductive system and breast disorders			
penis disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[12]	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
prostatomegaly			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[13]	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	17 / 371 (4.58%)	14 / 374 (3.74%)	17 / 376 (4.52%)
occurrences (all)	18	14	18
oropharyngeal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	10 / 374 (2.67%)	5 / 376 (1.33%)
occurrences (all)	10	12	5
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	14 / 371 (3.77%)	11 / 374 (2.94%)	12 / 376 (3.19%)
occurrences (all)	15	11	12
depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	14 / 371 (3.77%)	17 / 374 (4.55%)	3 / 376 (0.80%)
occurrences (all)	14	18	3
insomnia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	13 / 371 (3.50%)	21 / 374 (5.61%)	15 / 376 (3.99%)
occurrences (all)	13	22	18
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	2 / 374 (0.53%)	3 / 376 (0.80%)
occurrences (all)	8	2	3
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 371 (2.96%)	5 / 374 (1.34%)	9 / 376 (2.39%)
occurrences (all)	13	7	18
fall			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 371 (1.62%)	2 / 374 (0.53%)	9 / 376 (2.39%)
occurrences (all)	6	2	10
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	11 / 374 (2.94%)	12 / 376 (3.19%)
occurrences (all)	8	11	12
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	34 / 371 (9.16%)	37 / 374 (9.89%)	34 / 376 (9.04%)
occurrences (all)	47	50	52
migraine			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	14 / 374 (3.74%)	8 / 376 (2.13%)
occurrences (all)	8	17	9
Blood and lymphatic system disorders			
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	4 / 374 (1.07%)	3 / 376 (0.80%)
occurrences (all)	8	8	3
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	8 / 374 (2.14%)	9 / 376 (2.39%)
occurrences (all)	7	8	12
abdominal pain upper			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 371 (2.96%)	13 / 374 (3.48%)	8 / 376 (2.13%)
occurrences (all)	16	13	9
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 371 (1.62%)	9 / 374 (2.41%)	11 / 376 (2.93%)
occurrences (all)	6	9	13
diarrhoea			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	25 / 371 (6.74%)	21 / 374 (5.61%)	32 / 376 (8.51%)
occurrences (all)	29	30	37
dyspepsia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 371 (2.96%)	5 / 374 (1.34%)	13 / 376 (3.46%)
occurrences (all)	14	7	16
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	7 / 374 (1.87%)	8 / 376 (2.13%)
occurrences (all)	8	7	8
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	23 / 371 (6.20%)	21 / 374 (5.61%)	35 / 376 (9.31%)
occurrences (all)	25	24	42
toothache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	3 / 374 (0.80%)	3 / 376 (0.80%)
occurrences (all)	10	3	3
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	17 / 371 (4.58%)	9 / 374 (2.41%)	17 / 376 (4.52%)
occurrences (all)	21	12	20
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	5 / 371 (1.35%)	10 / 374 (2.67%)	7 / 376 (1.86%)
occurrences (all)	5	11	7
rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	7 / 374 (1.87%)	8 / 376 (2.13%)
occurrences (all)	12	7	12
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	18 / 371 (4.85%)	15 / 374 (4.01%)	15 / 376 (3.99%)
occurrences (all)	21	16	18
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	26 / 371 (7.01%)	21 / 374 (5.61%)	17 / 376 (4.52%)
occurrences (all)	27	27	20
bursitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 371 (1.08%)	9 / 374 (2.41%)	2 / 376 (0.53%)
occurrences (all)	4	9	2
musculoskeletal chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	18 / 371 (4.85%)	12 / 374 (3.21%)	9 / 376 (2.39%)
occurrences (all)	19	14	9
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	9 / 374 (2.41%)	10 / 376 (2.66%)
occurrences (all)	8	9	10
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	10 / 374 (2.67%)	3 / 376 (0.80%)
occurrences (all)	8	10	5
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	18 / 371 (4.85%)	25 / 374 (6.68%)	22 / 376 (5.85%)
occurrences (all)	22	29	28
cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 371 (0.81%)	3 / 374 (0.80%)	7 / 376 (1.86%)
occurrences (all)	3	4	9
conjunctivitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	4 / 371 (1.08%)	8 / 374 (2.14%)	6 / 376 (1.60%)
occurrences (all)	4	8	6
cystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	12 / 374 (3.21%)	4 / 376 (1.06%)
occurrences (all)	9	14	4
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	10 / 371 (2.70%)	10 / 374 (2.67%)	13 / 376 (3.46%)
occurrences (all)	14	10	14
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 371 (1.89%)	3 / 374 (0.80%)	7 / 376 (1.86%)
occurrences (all)	7	3	7
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 371 (1.62%)	10 / 374 (2.67%)	6 / 376 (1.60%)
occurrences (all)	7	10	6
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	12 / 371 (3.23%)	17 / 374 (4.55%)	6 / 376 (1.60%)
occurrences (all)	15	20	7
lower respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	1 / 374 (0.27%)	3 / 376 (0.80%)
occurrences (all)	12	1	4
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	24 / 371 (6.47%)	18 / 374 (4.81%)	32 / 376 (8.51%)
occurrences (all)	28	22	41
oral herpes			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 371 (1.08%)	10 / 374 (2.67%)	5 / 376 (1.33%)
occurrences (all)	5	14	7

pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 371 (2.96%)	9 / 374 (2.41%)	18 / 376 (4.79%)
occurrences (all)	12	9	18
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	26 / 371 (7.01%)	27 / 374 (7.22%)	19 / 376 (5.05%)
occurrences (all)	26	30	23
tooth abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 371 (0.27%)	5 / 374 (1.34%)	8 / 376 (2.13%)
occurrences (all)	1	6	8
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	58 / 371 (15.63%)	44 / 374 (11.76%)	45 / 376 (11.97%)
occurrences (all)	74	60	63
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	53 / 371 (14.29%)	60 / 374 (16.04%)	63 / 376 (16.76%)
occurrences (all)	80	81	86
vaginal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[14]	7 / 341 (2.05%)	5 / 344 (1.45%)	2 / 349 (0.57%)
occurrences (all)	9	7	2
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 371 (2.43%)	2 / 374 (0.53%)	6 / 376 (1.60%)
occurrences (all)	9	2	8
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 371 (2.16%)	8 / 374 (2.14%)	1 / 376 (0.27%)
occurrences (all)	10	8	1

Non-serious adverse events	LY2127399 Every 2 Weeks Follow-up	LY2127399 Every 4 Weeks Follow-up	Placebo Follow-up Period

	Period	Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 72 (29.17%)	19 / 78 (24.36%)	14 / 66 (21.21%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[11]	1 / 67 (1.49%)	0 / 74 (0.00%)	2 / 63 (3.17%)
occurrences (all)	1	0	2
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	2	0	0
fatigue			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
injection site reaction			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	3 / 66 (4.55%)
occurrences (all)	0	0	3
Reproductive system and breast disorders			
penis disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[12]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[13]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	2	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0

depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	1	1	0
insomnia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	3 / 78 (3.85%)	1 / 66 (1.52%)
occurrences (all)	0	3	1
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	2	1	0
migraine			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0

Blood and lymphatic system disorders			
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
dyspepsia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	3 / 78 (3.85%)	0 / 66 (0.00%)
occurrences (all)	1	3	0
toothache			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	2 / 78 (2.56%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	2 / 78 (2.56%)	0 / 66 (0.00%)
occurrences (all)	1	3	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used:			

MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	2 / 66 (3.03%)
occurrences (all)	0	1	2
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	2 / 78 (2.56%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	2 / 78 (2.56%)	1 / 66 (1.52%)
occurrences (all)	0	2	1
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	2	0	1
herpes zoster			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	1	0	1
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	1 / 78 (1.28%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
lower respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 72 (1.39%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
oral herpes			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	0 / 78 (0.00%)	1 / 66 (1.52%)
occurrences (all)	2	0	1
pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	1 / 78 (1.28%)	1 / 66 (1.52%)
occurrences (all)	2	1	1
tooth abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 72 (2.78%)	1 / 78 (1.28%)	0 / 66 (0.00%)
occurrences (all)	2	1	0

urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 72 (5.56%)	3 / 78 (3.85%)	3 / 66 (4.55%)
occurrences (all)	6	3	4
vaginal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[14]	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 72 (0.00%)	0 / 78 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0

Notes:

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male participants. The number of subjects exposed has been adjusted accordingly.
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male participants. The number of subjects exposed has been adjusted accordingly.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in female participants. The number of subjects exposed has been adjusted accordingly.

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.

Due to product program termination, not all analyses were completed.

Notes: