



Clinical trial results:

A Phase 3b, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of Subcutaneous LY2127399 in Participants with Systemic Lupus Erythematosus (SLE) (Illuminate-X)

Summary

EudraCT number	2010-022101-18
Trial protocol	AT HU ES LV BG IT GB DE HR
Global end of trial date	20 October 2015

Results information

Result version number	v1 (current)
This version publication date	11 April 2018
First version publication date	11 April 2018

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDX
-----------------------	-------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01488708
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number : 13811

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	06 January 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 October 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of this SLE study is to evaluate the long-term safety and efficacy of LY2127399 in eligible SLE participants who have completed the core studies (NCT01196091) (NCT01205438).

The trial was terminated early due to lack of efficacy.

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	06 January 2012
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	United States: 532
Country: Number of subjects enrolled	Puerto Rico: 15
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Peru: 69
Country: Number of subjects enrolled	Brazil: 54
Country: Number of subjects enrolled	Mexico: 51
Country: Number of subjects enrolled	Ecuador: 41
Country: Number of subjects enrolled	Argentina: 39
Country: Number of subjects enrolled	Colombia: 30
Country: Number of subjects enrolled	Guatemala: 30
Country: Number of subjects enrolled	Chile: 10
Country: Number of subjects enrolled	Philippines: 59
Country: Number of subjects enrolled	Taiwan: 42
Country: Number of subjects enrolled	Japan: 36
Country: Number of subjects enrolled	Korea, Republic of: 29
Country: Number of subjects enrolled	Thailand: 24
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	New Zealand: 5
Country: Number of subjects enrolled	Malaysia: 2

Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	Serbia: 63
Country: Number of subjects enrolled	Hungary: 44
Country: Number of subjects enrolled	Poland: 41
Country: Number of subjects enrolled	Russian Federation: 38
Country: Number of subjects enrolled	Ukraine: 31
Country: Number of subjects enrolled	Romania: 23
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Belarus: 11
Country: Number of subjects enrolled	Bulgaria: 11
Country: Number of subjects enrolled	Latvia: 9
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 8
Country: Number of subjects enrolled	Austria: 4
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Croatia: 2
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Tunisia: 40
Country: Number of subjects enrolled	South Africa: 31
Country: Number of subjects enrolled	Israel: 22
Country: Number of subjects enrolled	Egypt: 9
Country: Number of subjects enrolled	United Kingdom: 5
Worldwide total number of subjects	1518
EEA total number of subjects	181

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)	1474
From 65 to 84 years	43
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	LY 2127399 Q2W

Arm description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Arm type	Experimental
Investigational medicinal product name	LY2127399 every 2 weeks
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Arm title	LY2127399 Q4W
------------------	---------------

Arm description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Arm type	Experimental
Investigational medicinal product name	LY2127399 every 4 weeks
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Number of subjects in period 1	LY 2127399 Q2W	LY2127399 Q4W
Started	940	578
Received at least 1 Dose of Study Drug	937	578
Participated in Follow Up	810	526
Completed	0	0
Not completed	940	578
Study Termination	940	578

Baseline characteristics

Reporting groups

Reporting group title	LY 2127399 Q2W
-----------------------	----------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Reporting group title	LY2127399 Q4W
-----------------------	---------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Reporting group values	LY 2127399 Q2W	LY2127399 Q4W	Total
Number of subjects	940	578	1518
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn - gestational age < 37 0 wk	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	910	564	1474
From 65 to 84 years	29	14	43
85 years and over	1	0	1
Gender, Male/Female Units:			
Male	60	51	111
Female	880	527	1407
Race Stratification Units: Subjects			
Black or African American	138	45	183
Non-black or Non-African American	802	533	1335

Race			
Units: Subjects			
American Indian or Alaska Native	104	94	198
Asian	113	96	209
Black or African American	130	33	163
Native Hawaiian or Other Pacific Islander	0	1	1
White	579	337	916
Multiple	14	17	31
Ethnicity			
Units: Subjects			
Hispanic or Latino	265	189	454
Not Hispanic or Latino	612	314	926
Not Applicable	63	75	138
Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI) Score [1] Mean (Stand			
Units: units on a scale			
arithmetic mean	5.4	4.9	
standard deviation	± 3.81	± 3.74	-

End points

End points reporting groups

Reporting group title	LY 2127399 Q2W
-----------------------	----------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Reporting group title	LY2127399 Q4W
-----------------------	---------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Primary: Number of Adverse Events (AEs)

End point title	Number of Adverse Events (AEs) ^[1]
-----------------	---

End point description:

A summary of other non-serious adverse events and all serious adverse events, regardless of causality, is located in the Reported Adverse Events Section.

End point type	Primary
----------------	---------

End point timeframe:

Baseline through 4 years

Notes:

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

Justification: No statistical analysis was performed as per protocol. It was a number value of Adverse Events (AEs).

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	937 ^[2]	578 ^[3]		
Units: participants				
number (not applicable)	73.3	65.6		

Notes:

[2] - All participants who received at least 1 dose of study drug.

[3] - All participants who received at least 1 dose of study drug.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with a systemic lupus erythematosus (SLE) responder index (SRI) response

End point title	Proportion of participants with a systemic lupus erythematosus (SLE) responder index (SRI) response
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

Week 48

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[4]	0 ^[5]		
Units: participants				
number (not applicable)				

Notes:

[4] - Zero participants were analyzed due to early termination of the study.

[5] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with a reduction in steroid dose

End point title	Proportion of participants with a reduction in steroid dose
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline through 4 years

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[6]	0 ^[7]		
Units: participants				
number (not applicable)				

Notes:

[6] - Zero participants were analyzed due to early termination of the study.

[7] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in SLE Disease Activity Index

End point title Change in SLE Disease Activity Index

End point description:

End point type Secondary

End point timeframe:

Baseline, 4 years

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[8]	0 ^[9]		
Units: percent				
number (not applicable)				

Notes:

[8] - Zero participants were analyzed due to early termination of the study.

[9] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Occurrence of new severe SLE flares

End point title Occurrence of new severe SLE flares

End point description:

End point type Secondary

End point timeframe:

Baseline through 4 years

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[10]	0 ^[11]		
Units: count				
number (not applicable)				

Notes:

[10] - Zero participants were analyzed due to early termination of the study.

[11] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with improvement in Lupus Quality of Life

End point title	Proportion of participants with improvement in Lupus Quality of Life
-----------------	--

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

4 years

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[12]	0 ^[13]		
Units: percent				
number (not applicable)				

Notes:

[12] - Zero participants were analyzed due to early termination of the study.

[13] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in anti-double-stranded deoxyribonucleic acid level

End point title	Change in anti-double-stranded deoxyribonucleic acid level
-----------------	--

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline, 4 years

End point values	LY 2127399 Q2W	LY2127399 Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[14]	0 ^[15]		
Units: percent				
number (not applicable)				

Notes:

[14] - Zero participants were analyzed due to early termination of the study.

[15] - Zero participants were analyzed due to early termination of the study.

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-BCDX

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	17.1
--------------------	------

Reporting groups

Reporting group title	LY 2127399 Q2W Treatment
-----------------------	--------------------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Reporting group title	LY2127399 Q4W Treatment Period
-----------------------	--------------------------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Reporting group title	LY 2127399 Q2W Follow Up
-----------------------	--------------------------

Reporting group description:

If participant received LY2127399 in core study, 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo during core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks. Follow up.n

Reporting group title	LY2127399 Q4W Follow Up
-----------------------	-------------------------

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment. Follow up.

Serious adverse events	LY 2127399 Q2W Treatment	LY2127399 Q4W Treatment Period	LY 2127399 Q2W Follow Up
Total subjects affected by serious adverse events			
subjects affected / exposed	129 / 937 (13.77%)	64 / 578 (11.07%)	41 / 810 (5.06%)
number of deaths (all causes)	5	2	2
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign breast neoplasm			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
benign vaginal neoplasm			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[1]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (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
breast cancer			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
brenner tumour			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[2]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (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

haemangioma				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
neuroendocrine tumour				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
prostate cancer				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[3]	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 50 (0.00%)	
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 skin				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
squamous cell carcinoma of the cervix				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[4]	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 760 (0.00%)	
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 cancer				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[5]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (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 leiomyoma				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed ^[6]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
extremity necrosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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 17.1			
subjects affected / exposed	4 / 937 (0.43%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infarction			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
orthostatic hypotension			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
poor venous access			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
shock haemorrhagic			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombophlebitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
vasculitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
venous occlusion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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

venous thrombosis limb alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 937 (0.00%) 0 / 0 0 / 0	1 / 578 (0.17%) 0 / 1 0 / 0	0 / 810 (0.00%) 0 / 0 0 / 0
Pregnancy, puerperium and perinatal conditions abortion alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[7] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 877 (0.11%) 0 / 1 0 / 0	0 / 527 (0.00%) 0 / 0 0 / 0	0 / 810 (0.00%) 0 / 0 0 / 0
abortion spontaneous alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[8] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 877 (0.11%) 0 / 1 0 / 0	1 / 527 (0.19%) 0 / 1 0 / 0	0 / 810 (0.00%) 0 / 0 0 / 0
blighted ovum alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[9] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 937 (0.00%) 0 / 0 0 / 0	0 / 578 (0.00%) 0 / 0 0 / 0	0 / 760 (0.00%) 0 / 0 0 / 0
ectopic pregnancy alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[10] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 877 (0.11%) 0 / 1 0 / 0	0 / 527 (0.00%) 0 / 0 0 / 0	1 / 760 (0.13%) 0 / 1 0 / 0
General disorders and administration site conditions death alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all device dislocation	0 / 937 (0.00%) 0 / 0 0 / 0	1 / 578 (0.17%) 0 / 1 0 / 1	0 / 810 (0.00%) 0 / 0 0 / 0

alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
implant site erosion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
medical device complication			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	3 / 810 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic mass			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	2 / 810 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
benign prostatic hyperplasia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[11]	0 / 60 (0.00%)	1 / 51 (1.96%)	0 / 50 (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
dysmenorrhoea alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[12]	0 / 877 (0.00%)	1 / 527 (0.19%)	0 / 760 (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
metrorrhagia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[13]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (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
ovarian cyst alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[14]	0 / 877 (0.00%)	1 / 527 (0.19%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory distress syndrome alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 respiratory failure alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atelectasis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 17.1			
subjects affected / exposed	4 / 937 (0.43%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemoptysis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
hypoxia			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural fibrosis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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 congestion alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	2 / 810 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary haemorrhage alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 oedema alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
upper airway obstruction alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
conversion disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
delirium tremens alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			

subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
generalised anxiety disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
suicide attempt			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
electrocardiogram qrs complex shortened			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipase increased			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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			
ankle fracture			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bone fissure			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
bronchial injury			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
concussion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
contusion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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

femur fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gun shot wound			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
ligament rupture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
ligament sprain			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle strain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
overdose			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
procedural intestinal perforation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
respiratory fume inhalation disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
road traffic accident			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
spinal compression fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 937 (0.32%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

subdural haematoma alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vascular pseudoaneurysm alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 937 (0.32%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
angina pectoris alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
atrioventricular block alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block complete alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
atrioventricular block second degree alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
bundle branch block bilateral alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
cardiac failure congestive alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
cardio-respiratory arrest alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 17.1			
subjects affected / exposed	2 / 937 (0.21%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial fibrosis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

myocardial infarction			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
pericarditis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	0 / 810 (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
right ventricular failure			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	2 / 578 (0.35%)	0 / 810 (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
tricuspid valve disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery dissection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
epilepsy alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
third nerve disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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

migraine				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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	
neuropathy peripheral				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
neuropsychiatric lupus				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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	
optic neuritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
subarachnoid haemorrhage				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
syncope				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 937 (0.00%)	2 / 578 (0.35%)	0 / 810 (0.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
tension headache				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viith nerve paralysis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
vith nerve disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
Blood and lymphatic system disorders			
anaemia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
anaemia macrocytic alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
autoimmune haemolytic anaemia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
febrile neutropenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
haemolytic anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemolytic uraemic syndrome			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
histiocytosis haematophagic			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 17.1			
subjects affected / exposed	3 / 937 (0.32%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

leukopenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
lymphopenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
microcytic anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
neutropenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytopenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombotic thrombocytopenic purpura			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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			
amaurosis fugax			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cataract			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diplopia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eyelid ptosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	4 / 937 (0.43%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
constipation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
gastric ulcer perforation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 17.1			
subjects affected / exposed	3 / 937 (0.32%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis erosive			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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

gastroesophageal reflux disease alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
haemorrhoidal haemorrhage alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
hiatus hernia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal ischaemia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal perforation alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
large intestine polyp alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	0 / 810 (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
pancreatitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
small intestinal obstruction			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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			
cholecystitis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	3 / 937 (0.32%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug-induced liver injury alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic function abnormal alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
liver disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

nodular regenerative hyperplasia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dry gangrene alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
mucocutaneous ulceration alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
precancerous skin lesion alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
psoriasis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin ulcer alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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			
bladder prolapse			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
calculus ureteric			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydronephrosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 nephritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	2 / 810 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure acute			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
adrenocortical insufficiency acute			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mineralocorticoid deficiency			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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			
arthritis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
back pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
costochondritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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

muscle haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
muscular weakness			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
osteoarthritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	8 / 937 (0.85%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sle arthritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal osteoarthritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
systemic lupus erythematosus			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	4 / 937 (0.43%)	3 / 578 (0.52%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 4	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
amoebiasis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 17.1			
subjects affected / exposed	2 / 937 (0.21%)	2 / 578 (0.35%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bacteraemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blastocystis infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
brain abscess			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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

bronchitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	1 / 810 (0.12%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
bronchitis bacterial				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
cellulitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	3 / 937 (0.32%)	1 / 578 (0.17%)	1 / 810 (0.12%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
cervicitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[15]	0 / 877 (0.00%)	1 / 527 (0.19%)	0 / 810 (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	
cytomegalovirus infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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	
diverticulitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
enterocolitis bacterial				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia urinary tract infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
gastroenteritis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 937 (0.21%)	0 / 578 (0.00%)	0 / 810 (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
groin abscess alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster disseminated alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
infectious colitis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
kidney infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
localised infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
meningitis cryptococcal			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
meningitis viral			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
oesophageal candidiasis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
ophthalmic herpes zoster			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
oral fungal infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
peritonitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
peritonsillar abscess			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
pharyngotonsillitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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

pneumococcal sepsis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	11 / 937 (1.17%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	8 / 12	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
post procedural infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
pyelonephritis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
pyonephrosis alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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 tract infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
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 17.1			
subjects affected / exposed	3 / 937 (0.32%)	1 / 578 (0.17%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	1 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
sepsis syndrome alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
septic shock alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
sinusitis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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 sepsis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

staphylococcal skin infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
subcutaneous abscess alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tooth abscess alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
upper respiratory tract infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 937 (0.32%)	1 / 578 (0.17%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 937 (0.32%)	3 / 578 (0.52%)	2 / 810 (0.25%)
occurrences causally related to treatment / all	2 / 3	2 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicella alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	1 / 578 (0.17%)	0 / 810 (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
viral infection alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval cellulitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[16]	1 / 877 (0.11%)	0 / 527 (0.00%)	0 / 810 (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
Metabolism and nutrition disorders			
cholesterosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
diabetes mellitus			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	0 / 810 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
hyperglycaemia			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
hypoglycaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	2 / 578 (0.35%)	0 / 810 (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
ketosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 937 (0.11%)	0 / 578 (0.00%)	0 / 810 (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
metabolic acidosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 937 (0.00%)	0 / 578 (0.00%)	1 / 810 (0.12%)
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 Q4W Follow Up		
Total subjects affected by serious adverse events			
subjects affected / exposed	38 / 526 (7.22%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
benign breast neoplasm			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
benign vaginal neoplasm				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[1]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
breast cancer				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
brenner tumour				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[2]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemangioma				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neuroendocrine tumour				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostate cancer				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[3]	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

squamous cell carcinoma of skin alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
squamous cell carcinoma of the cervix alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[4] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 482 (0.21%) 0 / 1 0 / 0			
uterine cancer alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[5] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
uterine leiomyoma alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[6] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
Vascular disorders deep vein thrombosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
extremity necrosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
hypertension alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypotension				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
infarction				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
orthostatic hypotension				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral arterial occlusive disease				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
poor venous access				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
shock haemorrhagic				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

thrombophlebitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vasculitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
venous occlusion				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
venous thrombosis limb				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
abortion				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[7]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abortion spontaneous				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[8]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
blighted ovum				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed ^[9]	1 / 482 (0.21%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
ectopic pregnancy			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[10]	0 / 482 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
device dislocation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
implant site erosion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
medical device complication			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pelvic mass			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyrexia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[11]	1 / 44 (2.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
dysmenorrhoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[12]	1 / 482 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
metrorrhagia			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed ^[13]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ovarian cyst				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[14]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
acute respiratory distress syndrome				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
acute respiratory failure				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
asthma				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atelectasis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dyspnoea				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemoptysis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypoxia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
interstitial lung disease				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleural effusion				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleural fibrosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

pulmonary congestion alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
pulmonary embolism alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
pulmonary haemorrhage alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 1			
pulmonary hypertension alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
pulmonary oedema alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
upper airway obstruction alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
conversion disorder				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
delirium tremens				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
depression				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
generalised anxiety disorder				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
mental status changes				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
suicide attempt				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Investigations			
electrocardiogram qrs complex shortened			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lipase increased			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bone fissure			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bronchial injury			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
concussion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
contusion			

alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
femoral neck fracture				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
femur fracture				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fibula fracture				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gun shot wound				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
head injury				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
joint injury				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament rupture				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament sprain				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
muscle strain				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
overdose				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
procedural intestinal perforation				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

respiratory fume inhalation disorder alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
road traffic accident alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
spinal compression fracture alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
subdural haematoma alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
vascular pseudoaneurysm alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
Cardiac disorders acute myocardial infarction alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
angina pectoris alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrioventricular block				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrioventricular block complete				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrioventricular block second degree				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bundle branch block bilateral				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac arrest				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure congestive				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

cardio-respiratory arrest				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery disease				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial fibrosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pericardial effusion				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pericarditis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
right ventricular failure				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
tachycardia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
tricuspid valve disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
carotid artery dissection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
cerebrovascular disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
epilepsy			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
headache				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
hemiparesis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
iiiird nerve disorder				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
migraine				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neuropathy peripheral				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neuropsychiatric lupus				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

optic neuritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
subarachnoid haemorrhage				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
syncope				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tension headache				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
viith nerve paralysis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vith nerve disorder				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
anaemia macrocytic			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
febrile neutropenia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
haemolytic anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
haemolytic uraemic syndrome			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
haemorrhagic anaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
histiocytosis haematophagic				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
iron deficiency anaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
leukopenia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lymphopenia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
microcytic anaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

neutropenia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
thrombocytopenia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
thrombotic thrombocytopenic purpura				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
vertigo				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
amaurosis fugax				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
cataract				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diplopia				

alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
eyelid ptosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
abdominal pain				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
colitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
colitis ulcerative				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
constipation				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastric ulcer perforation				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastritis erosive				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhoidal haemorrhage				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hiatus hernia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

intestinal ischaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intestinal perforation				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
large intestine polyp				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophagitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatitis acute				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rectal haemorrhage				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	1 / 526 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
retroperitoneal haemorrhage alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
small intestinal obstruction alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholecystitis acute alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholecystitis chronic alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholelithiasis alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
drug-induced liver injury alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
hepatic function abnormal alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
liver disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
nodular regenerative hyperplasia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
angioedema alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
dry gangrene alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
mucocutaneous ulceration			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
precancerous skin lesion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
psoriasis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
skin ulcer			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
bladder prolapse			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
calculus ureteric			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
glomerulonephritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hydronephrosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lupus nephritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	3 / 526 (0.57%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
nephrolithiasis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
renal failure acute				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
urinary retention				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
adrenocortical insufficiency acute			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
mineralocorticoid deficiency			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
back pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bursitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
chondrocalcinosis pyrophosphate			

alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
costochondritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intervertebral disc protrusion				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lumbar spinal stenosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
muscle haemorrhage				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
muscular weakness				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
musculoskeletal chest pain				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
musculoskeletal pain				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
osteonecrosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pain in extremity				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
sle arthritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal osteoarthritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

systemic lupus erythematosus alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 526 (0.76%) 0 / 4 0 / 0			
tendon disorder alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
Infections and infestations abdominal abscess alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
abscess alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
amoebiasis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
appendicitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
arthritis bacterial alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
blastocystis infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
brain abscess				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis bacterial				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

cervicitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed ^[15]	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cytomegalovirus infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
enterocolitis bacterial				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
escherichia urinary tract infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
groin abscess				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
herpes zoster				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	2 / 526 (0.38%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
herpes zoster disseminated				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
infectious colitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
influenza				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
kidney infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
lobar pneumonia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

localised infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meningitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meningitis cryptococcal				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meningitis viral				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophageal candidiasis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ophthalmic herpes zoster				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oral fungal infection				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peritonitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peritonsillar abscess				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pharyngotonsillitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumococcal sepsis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
pneumonia bacterial				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

post procedural infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
pulmonary tuberculosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
pyelonephritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
pyonephrosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
sepsis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
sepsis syndrome alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
septic shock				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sinusitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
staphylococcal sepsis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
staphylococcal skin infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
subcutaneous abscess				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
tooth abscess				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

upper respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
urinary tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 526 (0.57%) 0 / 3 0 / 0			
varicella alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
viral infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 526 (0.19%) 0 / 1 0 / 0			
vulval cellulitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[16] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 526 (0.00%) 0 / 0 0 / 0			
Metabolism and nutrition disorders cholesterosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all dehydration alternative dictionary used: MedDRA 17.1	0 / 526 (0.00%) 0 / 0 0 / 0			

subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetes mellitus				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	1 / 526 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
diabetes mellitus inadequate control				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hyperglycaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypoglycaemia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ketosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
metabolic acidosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 526 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

[16] - 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 male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	LY 2127399 Q2W Treatment	LY2127399 Q4W Treatment Period	LY 2127399 Q2W Follow Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	464 / 937 (49.52%)	232 / 578 (40.14%)	110 / 810 (13.58%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	27 / 937 (2.88%)	8 / 578 (1.38%)	3 / 810 (0.37%)
occurrences (all)	27	10	3
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	18 / 937 (1.92%)	12 / 578 (2.08%)	2 / 810 (0.25%)
occurrences (all)	19	13	2
headache			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	53 / 937 (5.66%)	28 / 578 (4.84%)	13 / 810 (1.60%)
occurrences (all)	67	34	13
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	19 / 937 (2.03%)	7 / 578 (1.21%)	0 / 810 (0.00%)
occurrences (all)	20	7	0
pyrexia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	20 / 937 (2.13%)	4 / 578 (0.69%)	3 / 810 (0.37%)
occurrences (all)	25	4	4
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	21 / 937 (2.24%)	3 / 578 (0.52%)	2 / 810 (0.25%)
occurrences (all)	21	3	2
abdominal pain upper			
alternative dictionary used:			

MedDRA 17.1			
subjects affected / exposed	9 / 937 (0.96%)	12 / 578 (2.08%)	5 / 810 (0.62%)
occurrences (all)	9	12	5
diarrhoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	59 / 937 (6.30%)	18 / 578 (3.11%)	7 / 810 (0.86%)
occurrences (all)	70	21	7
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	23 / 937 (2.45%)	7 / 578 (1.21%)	0 / 810 (0.00%)
occurrences (all)	24	7	0
nausea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	34 / 937 (3.63%)	12 / 578 (2.08%)	6 / 810 (0.74%)
occurrences (all)	36	14	6
vomiting			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	21 / 937 (2.24%)	10 / 578 (1.73%)	3 / 810 (0.37%)
occurrences (all)	23	10	4
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	28 / 937 (2.99%)	10 / 578 (1.73%)	9 / 810 (1.11%)
occurrences (all)	29	13	9
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	23 / 937 (2.45%)	6 / 578 (1.04%)	0 / 810 (0.00%)
occurrences (all)	28	8	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	21 / 937 (2.24%)	10 / 578 (1.73%)	3 / 810 (0.37%)
occurrences (all)	21	11	3
insomnia			

alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	18 / 937 (1.92%) 18	12 / 578 (2.08%) 12	4 / 810 (0.49%) 4
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	33 / 937 (3.52%) 39 36 / 937 (3.84%) 39 27 / 937 (2.88%) 29	12 / 578 (2.08%) 16 17 / 578 (2.94%) 17 6 / 578 (1.04%) 8	10 / 810 (1.23%) 11 6 / 810 (0.74%) 6 5 / 810 (0.62%) 5
Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) nasopharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) sinusitis alternative dictionary used:	57 / 937 (6.08%) 74 14 / 937 (1.49%) 18 63 / 937 (6.72%) 83 27 / 937 (2.88%) 33	26 / 578 (4.50%) 32 16 / 578 (2.77%) 16 40 / 578 (6.92%) 46 15 / 578 (2.60%) 16	10 / 810 (1.23%) 10 4 / 810 (0.49%) 4 12 / 810 (1.48%) 12 1 / 810 (0.12%) 1

MedDRA 17.1			
subjects affected / exposed	56 / 937 (5.98%)	17 / 578 (2.94%)	9 / 810 (1.11%)
occurrences (all)	64	28	9
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	104 / 937 (11.10%)	51 / 578 (8.82%)	18 / 810 (2.22%)
occurrences (all)	142	68	18
urinary tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	106 / 937 (11.31%)	52 / 578 (9.00%)	20 / 810 (2.47%)
occurrences (all)	158	78	21

Non-serious adverse events	LY2127399 Q4W Follow Up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	75 / 526 (14.26%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 526 (0.38%)		
occurrences (all)	2		
headache			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	6 / 526 (1.14%)		
occurrences (all)	6		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
pyrexia			
alternative dictionary used:			

MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
abdominal pain upper			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
diarrhoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 526 (0.38%)		
occurrences (all)	2		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
vomiting			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 526 (0.19%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 526 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			

rash alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	1 / 526 (0.19%) 1		
Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	1 / 526 (0.19%) 1 3 / 526 (0.57%) 3		
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	3 / 526 (0.57%) 3 4 / 526 (0.76%) 4 3 / 526 (0.57%) 3		
Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	8 / 526 (1.52%) 9 6 / 526 (1.14%) 6		

nasopharyngitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	8 / 526 (1.52%)		
occurrences (all)	8		
pharyngitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 526 (0.38%)		
occurrences (all)	2		
sinusitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 526 (0.57%)		
occurrences (all)	3		
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	11 / 526 (2.09%)		
occurrences (all)	12		
urinary tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	16 / 526 (3.04%)		
occurrences (all)	18		

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.

Insufficient data available for analysis since study terminated early due to lack of efficacy in parent studies.
--

Notes: