Clinical trial results:
A 12-Week Multicenter, Randomized, Double-Blind, Placebo Controlled Study Comparing the Efficacy and Safety of LY2439821 to Etanercept and Placebo in Patients with Moderate to Severe Plaque Psoriasis with a Long-Term Extension Period

Summary

EudraCT number	2011-004368-31
Trial protocol	HU DE BG PL
Global end of trial date	22 July 2019

Results information

Result version number	v1 (current)
This version publication date	02 August 2020
First version publication date	02 August 2020

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHBC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01646177
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13685

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 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	22 July 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will assess the safety and efficacy of ixekizumab (LY2439821), compared to etanercept and placebo in participants with moderate to severe chronic plaque psoriasis.

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	28 July 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	Argentina: 21
Country: Number of subjects enrolled	Chile: 76
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Bulgaria: 48
Country: Number of subjects enrolled	Germany: 312
Country: Number of subjects enrolled	Hungary: 113
Country: Number of subjects enrolled	Poland: 39
Country: Number of subjects enrolled	Russian Federation: 77
Country: Number of subjects enrolled	Canada: 152
Country: Number of subjects enrolled	United States: 503
Worldwide total number of subjects	1346
EEA total number of subjects	512

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)	1238
From 65 to 84 years	107
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

This study has 4 periods: Period 1 - Screening; Period 2 - Blinded Induction Dosing Period (Weeks 0 to 12); Period 3 - Long-Term Extension Period (Weeks 12 to 264); Period 4 - Post-Treatment Follow-Up Period (Minimum of 12 Weeks)

Period 1

Period 1 title	Blinded Induction Dosing (Week 0-12)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12.

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

Dosage and administration details:

Administered SC

Arm title	50 mg Etanercept (ETN)

Arm description:

Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12.
Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).

Arm type	Active comparator
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).

Arm title	80 mg ixekizumab Dosing Regimen 2 (Q4W)

Arm description:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8).

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10.

Arm title	80 mg ixekizumab Dosing Regimen 1 (Q2W)

Arm description:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).
Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

Number of subjects in period 1	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)
Started	193	382	386
Received at least one dose of study drug	193	382	382
Completed	183	369	360
Not completed	10	13	26
Consent withdrawn by subject	3	2	4
Physician decision	1	2	1
Adverse event, non-fatal	2	4	9
Lost to follow-up	3	2	2
Protocol deviation	1	3	8
Lack of efficacy	-	-	2

Number of subjects in period 1	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Started	385
Received at least one dose of study drug	384
Completed	363
Not completed	22
Consent withdrawn by subject	4
Physician decision	2
Adverse event, non-fatal	8
Lost to follow-up	-
Protocol deviation	7
Lack of efficacy	1

Period 2

Period 2 title	Long-Term Extension Period (Week 12-264)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	PBO/IXE80Q4W

Arm description:

Participants who received placebo during the induction period and received 80 mg ixekizumab SC injection every four weeks (IXE80Q4W) in the Long-term extension period.

Arm type	Experimental

Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a starting dose of 160 mg of ixekizumab as 2 SC injections at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

Arm title	ETN/IXE80Q4W

Arm description:

Participants who received Etanercept during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received placebo as 2 SC injections at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

Arm title	IXE80Q4W/IXE80Q4W

Arm description:

Participants who received 80 mg ixe Q4W during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received 80 mg ixekizumab as 1 SC injection + a placebo injection at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

Arm title	IXE80Q2W/IXE80Q4W

Arm description:

Participants who received 80 mg ixe Q2W (IXE80Q2W) during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received 80 mg ixekizumab as 1 SC injection + a placebo injection at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

Number of subjects in period 2	PBO/IXE80Q4W	ETN/IXE80Q4W	IXE80Q4W/IXE80Q4W
Started	183	369	360
Received at least one dose of study drug	183	369	360
Completed	135	256	244
Not completed	48	113	116
Adverse event, serious fatal	1	3	1
Parent/Caregiver Decision	-	-	-
Consent withdrawn by subject	11	30	29
Physician decision	3	5	5
Clinical Relapse	1	1	1
Adverse event, non-fatal	16	34	43
Sponsor Decision	3	2	2
Lost to follow-up	6	17	23
Missing Disposition Form	-	3	2
Lack of efficacy	6	14	10
Protocol deviation	1	4	-

Number of subjects in period 2	IXE80Q2W/IXE80Q4W
Started	362
Received at least one dose of study drug	362
Completed	255
Not completed	107
Adverse event, serious fatal	3
Parent/Caregiver Decision	1
Consent withdrawn by subject	27
Physician decision	5
Clinical Relapse	4
Adverse event, non-fatal	30
Sponsor Decision	2
Lost to follow-up	18
Missing Disposition Form	1
Lack of efficacy	11
Protocol deviation	5

Period 3

Period 3 title	Follow-Up Period (Minimum of 12 Weeks)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	PBO Follow-Up Period

Arm description:

Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period.

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

Dosage and administration details:

Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period.

Arm title	ETN Follow-Up Period

Arm description:

Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period.

Arm type	Active comparator
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period.

Arm title	IXE80Q4W Follow-Up Period

Arm description:

Participants who received 80 mg ixe Q4W in the Induction Period and entered the Post-Treatment Follow-up Period.

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

Dosage and administration details:

Participants who received 80 mg ixe Q4W in the Induction Period and entered the Post-Treatment Follow-up Period.

Arm title	IXE80Q2W Follow-Up Period

Arm description:

Participants who received 80 mg ixe Q2W in the Induction Period and entered the Post-Treatment Follow-up Period.

Arm type	Experimental

Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received 80 mg ixe Q2W in the Induction Period and entered the Post-Treatment Follow-up Period.

Number of subjects in period 3	PBO Follow-Up Period	ETN Follow-Up Period	IXE80Q4W Follow-Up Period
Started	157	309	305
Received at least one dose of study drug	157	309	305
Completed	126	233	225
Not completed	31	76	80
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	7	21	19
Physician decision	1	2	2
Clinical Relapse	-	1	1
Adverse event, non-fatal	13	28	34
Sponsor Decision	-	1	1
Lost to follow-up	4	8	9
Entry Criteria Not Met	-	-	1
Lack of efficacy	4	9	8
Protocol deviation	1	6	4

Number of subjects in period 3	IXE80Q2W Follow-Up Period
Started	313
Received at least one dose of study drug	313
Completed	230
Not completed	83
Adverse event, serious fatal	1
Consent withdrawn by subject	19
Physician decision	3
Clinical Relapse	3
Adverse event, non-fatal	30
Sponsor Decision	1
Lost to follow-up	9
Entry Criteria Not Met	1
Lack of efficacy	9
Protocol deviation	7

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12.	
Reporting group title	50 mg Etanercept (ETN)
Reporting group description:	
Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12. Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).	
Reporting group title	80 mg ixekizumab Dosing Regimen 2 (Q4W)
Reporting group description:	
A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.	
Reporting group title	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Reporting group description:	
A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.	

Reporting group values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects	193	382	386
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	180	349	358
>=65 years	13	33	28
Gender categorical Units: Subjects			
Female	56	113	128
Male	137	269	258
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	25	52	50
Not Hispanic or Latino	133	263	269
Unknown or Not Reported	35	67	67
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	4	4
Asian	7	11	11
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	8	10	9
White	176	351	360
More than one race	1	5	1
Unknown or Not Reported	0	0	0

Region of Enrollment Units: Subjects			
Argentina	2	7	6
Chile	11	21	22
Mexico	1	2	1
Bulgaria	9	12	14
Germany	45	87	90
Hungary	18	31	31
Poland	5	10	11
Russia	11	22	20
Canada	22	44	44
United States	69	146	147

Reporting group values	80 mg ixekizumab Dosing Regimen 1 (Q2W)	Total	
Number of subjects	385	1346	
Age categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	351	1238	
>=65 years	34	108	
Gender categorical Units: Subjects			
Female	131	428	
Male	254	918	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	57	184	
Not Hispanic or Latino	259	924	
Unknown or Not Reported	69	238	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	10	
Asian	12	41	
Native Hawaiian or Other Pacific Islander	4	6	
Black or African American	5	32	
White	361	1248	
More than one race	2	9	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
Argentina	6	21	
Chile	22	76	
Mexico	1	5	
Bulgaria	13	48	
Germany	90	312	
Hungary	33	113	
Poland	13	39	
Russia	24	77	
Canada	42	152	
United States	141	503	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12.	
Reporting group title	50 mg Etanercept (ETN)
Reporting group description:	
Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12. Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).	
Reporting group title	80 mg ixekizumab Dosing Regimen 2 (Q4W)
Reporting group description:	
A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.	
Reporting group title	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Reporting group description:	
A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.	
Reporting group title	PBO/IXE80Q4W
Reporting group description:	
Participants who received placebo during the induction period and received 80 mg ixekizumab SC injection every four weeks (IXE80Q4W) in the Long-term extension period.	
Reporting group title	ETN/IXE80Q4W
Reporting group description:	
Participants who received Etanercept during the induction period and received IXE80Q4W in the long-term extension period.	
Reporting group title	IXE80Q4W/IXE80Q4W
Reporting group description:	
Participants who received 80 mg ixe Q4W during the induction period and received IXE80Q4W in the long-term extension period.	
Reporting group title	IXE80Q2W/IXE80Q4W
Reporting group description:	
Participants who received 80 mg ixe Q2W (IXE80Q2W) during the induction period and received IXE80Q4W in the long-term extension period.	
Reporting group title	PBO Follow-Up Period
Reporting group description:	
Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period.	
Reporting group title	ETN Follow-Up Period
Reporting group description:	
Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period.	
Reporting group title	IXE80Q4W Follow-Up Period
Reporting group description:	
Participants who received 80 mg ixe Q4W in the Induction Period and entered the Post-Treatment Follow-up Period.	
Reporting group title	IXE80Q2W Follow-Up Period
Reporting group description:	
Participants who received 80 mg ixe Q2W in the Induction Period and entered the Post-Treatment Follow-up Period.	

Primary: Number of participants achieving a static Physician Global Assessment (sPGA) of (0, 1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

End point title	Number of participants achieving a static Physician Global Assessment (sPGA) of (0, 1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

End point description:

The sPGA is a physician's determination of the participant's psoriasis lesions overall at a given time point categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), or very severe (5). An sPGA (0,1) response was defined as a post-baseline sPGA score of 0 or 1. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193[1]	382[2]	386[3]	385[4]
Units: participants	13	159	291	310

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

[3] - All randomized participants.

[4] - All randomized participants.

Statistical analyses

Statistical analysis title	sPGA Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	575
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)

Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Primary: Number of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point title	Number of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 75 was defined as having an improvement of at least 75% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193[5]	382[6]	386[7]	385[8]
Units: participants	14	204	325	336

Notes:

[5] - All randomized participants.

[6] - All randomized participants.

[7] - All randomized participants.

[8] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI 75 Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	575
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 75 Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 75 Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of participants achieving an sPGA (0) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

End point title	Number of participants achieving an sPGA (0) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

End point description:

The sPGA is a physician’s determination of the participant’s psoriasis lesions overall at a given time point categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant’s psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), or very severe (5). An sPGA (0) response was defined as a post-baseline sPGA score of 0. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193[9]	382[10]	386[11]	385[12]
Units: participants	0	33	139	155

Notes:

[9] - All randomized participants.

[10] - All randomized participants.

[11] - All randomized participants.

[12] - All randomized participants.

Statistical analyses

Statistical analysis title	sPGA (0) Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) v Placebo
Number of subjects included in analysis	575
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA (0) Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA (0) Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants Achieving ≥90% (PASI 90) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point title	Number of Participants Achieving ≥90% (PASI 90) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 90 were defined as having an improvement of at least 90% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193[13]	382[14]	386[15]	385[16]
Units: participants	6	98	252	262

Notes:

[13] - All randomized participants.

[14] - All randomized participants.

[15] - All randomized participants.

[16] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI 90 Statisitical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	575
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 90 Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 90 Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)

Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants Achieving 100% (PASI 100) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point title	Number of Participants Achieving 100% (PASI 100) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 100 were defined as having an improvement of at least 100% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193[17]	382[18]	386[19]	385[20]
Units: participants	0	28	135	145

Notes:

[17] - All randomized participants.

[18] - All randomized participants.

[19] - All randomized participants.

[20] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI 100 Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	575
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 100 Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI 100 Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants Achieving an Itch Numeric Rating Scale (NRS) ≥4 Point Reduction [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

End point title	Number of Participants Achieving an Itch Numeric Rating Scale (NRS) ≥4 Point Reduction [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

End point description:

The Itch NRS is a participant-administered single-item 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Participants indicate their overall severity of itching from Psoriasis by circling the number that best describes the worst level of itching in the past 24 hours. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	158[21]	312[22]	313[23]	320[24]
Units: participants	33	200	250	264

Notes:

[21] - All randomized participants and had an Itch NRS score >=4 at baseline.

[22] - All randomized participants and had an Itch NRS score >=4 at baseline.

[23] - All randomized participants and had an Itch NRS score >=4 at baseline.

[24] - All randomized participants and had an Itch NRS score >=4 at baseline.

Statistical analyses

Statistical analysis title	Itch NRS Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	470
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Itch NRS Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	471
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Itch NRS Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	478
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

End point description:

The DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "not at all," "a lot," and "very much," with corresponding scores of 1, 2, and 3, respectively, and unanswered ("not relevant") responses scored as "0." Totals range from 0 to 30 (less to more impairment), and a 5 point change from baseline is considered clinically relevant. Least Square (LS) Means in total DLQI score were calculated using Mixed Model Repeated Measures (MMRM) with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	191[25]	376[26]	375[27]	377[28]
Units: Units on a Scale				
least squares mean (standard error)	-1.7 (± 0.32)	-8.0 (± 0.23)	-9.6 (± 0.23)	-10.2 (± 0.23)

Notes:

[25] - All randomized participants who had at least one post-dose measurement of DLQI.

[26] - All randomized participants who had at least one post-dose measurement of DLQI.

[27] - All randomized participants who had at least one post-dose measurement of DLQI.

[28] - All randomized participants who had at least one post-dose measurement of DLQI.

Statistical analyses

Statistical analysis title	DLQI Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) v Placebo
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	DLQI Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	DLQI Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	568
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Score

End point title	Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Score

End point description:

The NAPSI is a numeric, reproducible, objective tool used to evaluate the severity of fingernail bed psoriasis and fingernail matrix psoriasis by area of involvement in the fingernail unit. The fingernail is divided with imaginary horizontal and longitudinal lines into quadrants. Each fingernail is given a score for fingernail bed psoriasis: 0 (none) to 4 (psoriasis in 4 quadrants of the nail) and fingernail matrix psoriasis (0 to 4) depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed and fingernail matrix psoriasis in each quadrant. The NAPSI score of a fingernail is the sum of scores in fingernail bed and fingernail matrix from each quadrant (maximum of 8). Each fingernail is evaluated, and the sum of all the fingernails is the total NAPSI score (range, 0 to 80). LS Means in NAPSI score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	115[29]	233[30]	226[31]	228[32]
Units: Units on a Scale				
least squares mean (standard error)	1.6362 (± 1.0991)	-6.4015 (± 0.7716)	-9.9793 (± 0.7838)	-10.4145 (± 0.7820)

Notes:

[29] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[30] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[31] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[32] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

Statistical analyses

Statistical analysis title	NAPSI Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) v Placebo
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	NAPSI Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	341
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	NAPSI Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Percent of Body Surface Area (BSA) Involvement of Psoriasis

End point title	Percent of Body Surface Area (BSA) Involvement of Psoriasis

End point description:

Percentage involvement of psoriasis on each participants body surface area was assessed by the investigator on a continuous scale from 0% (no involvement) to 100% (full involvement), in which 1% corresponds to the size of the participant's hand (including palm, fingers and thumb). LS Means in BSA were calculated using MMRM with baseline BSA as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	192[33]	378[34]	377[35]	380[36]
Units: Percent				
least squares mean (standard error)	-0.7 (± 1.03)	-16.4 (± 0.73)	-23.2 (± 0.73)	-23.2 (± 0.73)

Notes:

[33] - All randomized participants and had at least one post-dose measurement of BSA.

[34] - All randomized participants and had at least one post-dose measurement of BSA.

[35] - All randomized participants and had at least one post-dose measurement of BSA.

[36] - All randomized participants and had at least one post-dose measurement of BSA.

Statistical analyses

Statistical analysis title	BSA Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)

Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	BSA Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	BSA Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Score	
End point title	Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Score
End point description:	
PSSI is a composite score ranging from 0 (best) to 72 (worst), derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of scalp area involved. LS Means in PSSI score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	175[37]	345[38]	344[39]	344[40]
Units: Units on a Scale				
least squares mean (standard error)	-5.0 (± 0.53)	-15.9 (± 0.38)	-18.2 (± 0.38)	-18.8 (± 0.38)

Notes:
[37] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.
[38] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.
[39] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.
[40] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.

Statistical analyses

Statistical analysis title	PSSI Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PSSI Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PSSI Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from Baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 Items (QIDS-SR16) Total Score [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

End point title	Change from Baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 Items (QIDS-SR16) Total Score [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

End point description:

The QIDS-SR16 is a self-administered, 16-item instrument in which a participant is asked to consider each statement as it relates to the way they have felt for the past 7 days. There is a 4-point scale for each item ranging from 0 (best) to 3 (worst). The 16 items are scored to give 9 individual depression domains (sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance [initial, middle and late insomnia or hypersomnia], decrease/increase in appetite/weight, and psychomotor agitation/retardation), which are summed to give a single score ranging from 0 to 27,

with higher scores denoting greater symptom severity. LS Means in total QIDS-SR16 score were calculated using the analysis of covariance (ANCOVA) model with treatment, pooled center and baseline QIDS total score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184[41]	379[42]	373[43]	373[44]
Units: Units on a Scale				
least squares mean (standard error)	-0.3 (± 0.20)	-0.5 (± 0.14)	-0.9 (± 0.14)	-1.3 (± 0.14)

Notes:

[41] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[42] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[43] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[44] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

Statistical analyses

Statistical analysis title	QIDS-SR16 Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) v Placebo
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.473
Method	ANCOVA

Statistical analysis title	QIDS-SR16 Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	557
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.015
Method	ANCOVA

Statistical analysis title	QIDS-SR16 Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)

Number of subjects included in analysis	557
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Secondary: Change From Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

End point title	Change From Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

End point description:

The SF-36 is a participant-reported outcome measure evaluating participant's health status. It comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. The 8 domains are regrouped into the PCS and MCS scores. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. In this study, the SF-36 acute version was used, which has a 1 week recall period. LS Means in SF-36 score were calculated using the ANCOVA model with treatment, pooled center and baseline SF-36 score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	179[45]	365[46]	362[47]	357[48]
Units: Units on a Scale				
least squares mean (standard error)				
PCS	-0.2 (± 0.51)	3.1 (± 0.36)	4.1 (± 0.36)	4.0 (± 0.36)
MCS	1.2 (± 0.58)	2.7 (± 0.40)	3.8 (± 0.41)	4.28 (± 0.41)

Notes:

[45] - All randomized participants and had at least one post-dose measurement of SF-36.

[46] - All randomized participants and had at least one post-dose measurement of SF-36.

[47] - All randomized participants and had at least one post-dose measurement of SF-36.

[48] - All randomized participants and had at least one post-dose measurement of SF-36.

Statistical analyses

Statistical analysis title	SF-36 Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)

Number of subjects included in analysis	544
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	541
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	541
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 4
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	544
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 5
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	541
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 6
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	536
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANCOVA

Secondary: Change From Baseline in Patient's Global Assessment of Disease Severity (PatGA)

End point title	Change From Baseline in Patient's Global Assessment of Disease Severity (PatGA)

End point description:

The Patient's Global Assessment of Disease Severity is a single-item participant-reported outcome measure on which participants are asked to rate the severity of their psoriasis "today" from 0 (Clear) = no psoriasis, to 5 (Severe) = the worst their psoriasis has ever been. LS Means in Patient's Global Assessment of Disease Severity score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	192[49]	377[50]	375[51]	376[52]
Units: Units on a Scale				
least squares mean (standard error)	-0.5 (± 0.08)	-2.3 (± 0.06)	-3.1 (± 0.06)	-3.1 (± 0.06)

Notes:

[49] - All randomized participants and had at least one post-dose measurement of PatGA.

[50] - All randomized participants and had at least one post-dose measurement of PatGA.

[51] - All randomized participants and had at least one post-dose measurement of PatGA.

[52] - All randomized participants and had at least one post-dose measurement of PatGA.

Statistical analyses

Statistical analysis title	PatGA Statistical Analysis 1
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PatGA Statistical Analysis 2
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PatGA Statistical Analysis 3
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	568
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Number of Participants Achieving Palmoplantar PASI ≥50% (PPASI 50) Improvement

End point title	Number of Participants Achieving Palmoplantar PASI ≥50% (PPASI 50) Improvement

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 50 were defined as having an improvement of at least 50% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54[53]	95[54]	87[55]	96[56]
Units: Participants	26	77	75	78

Notes:

[53] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[54] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[55] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[56] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

Statistical analysis title	Statistical Analysis 1 (PPASI 50)
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2 (PPASI 50)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 3 (PPASI 50)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants Achieving Palmoplantar PASI of ≥75% (PPASI 75) Improvement

End point title	Number of Participants Achieving Palmoplantar PASI of ≥75% (PPASI 75) Improvement

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 75 were defined as having an improvement of at least 75% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54[57]	95[58]	87[59]	96[60]
Units: Participants	19	63	69	72

Notes:

[57] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[58] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[59] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[60] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

Statistical analysis title	Statistical Analysis 1 (PPASI 75)
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2 (PPASI 75)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 3 (PPASI 75)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants Achieving Palmoplantar PASI of 100% (PPASI 100) Improvement

End point title	Number of Participants Achieving Palmoplantar PASI of 100% (PPASI 100) Improvement

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and

desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 100 were defined as having an improvement of 100% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54[61]	95[62]	87[63]	96[64]
Units: Participants	15	57	54	61

Notes:

[61] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[62] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[63] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[64] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

Statistical analysis title	Statistical Analysis 1 (PPASI 100)
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2 (PPASI 100)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 3 (PPASI 100)
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)

Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants With Treatment-Emergent Anti-Ixekizumab Antibodies

End point title	Number of Participants With Treatment-Emergent Anti-Ixekizumab Antibodies

End point description:

The percentage of participants with treatment-emergent positive anti-ixekizumab antibodies at any time post-baseline were summarized by treatment group. Percentage of participants with treatment-emergent positive anti-ixekizumab antibodies were calculated as: number of participants with an evaluable baseline sample and ≥1 evaluable post-baseline sample/number of participants in the analysis population * 100.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	191[65]	378[66]	378[67]	378[68]
Units: Participants	2	8	52	23

Notes:

[65] - All randomized participants who received at least one dose of study treatment and had evaluable data

[66] - All randomized participants who received at least one dose of study treatment and had evaluable data

[67] - All randomized participants who received at least one dose of study treatment and had evaluable data

[68] - All randomized participants who received at least one dose of study treatment and had evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Absenteeism of Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO)

End point title	Change From Baseline in Absenteeism of Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO)

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in

productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	120[69]	217[70]	230[71]	218[72]
Units: Units on a Scale				
least squares mean (standard error)	0.0 (± 0.82)	-2.8 (± 0.62)	-2.0 (± 0.60)	-2.5 (± 0.61)

Notes:

[69] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[70] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[71] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[72] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 1

Statistical analysis description:

Absenteeism Score

Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 2

Statistical analysis description:

Absenteeism Score

Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 3

Statistical analysis description: Absenteeism Score	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	338
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	ANCOVA

Secondary: Change From Baseline in Activity Impairment Score of WPAI-PSO

End point title	Change From Baseline in Activity Impairment Score of WPAI-PSO

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184[73]	376[74]	375[75]	373[76]
Units: Units on a Scale				
least squares mean (standard error)	-2.5 (± 1.30)	-21.1 (± 0.91)	-23.3 (± 0.92)	-24.5 (± 0.92)

Notes:

[73] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[74] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[75] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[76] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 4
Statistical analysis description: Activity Impairment Score	
Comparison groups	50 mg Etanercept (ETN) v Placebo

Number of subjects included in analysis	560
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 5
Statistical analysis description: Activity Impairment Score	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	559
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 6
Statistical analysis description: Activity Impairment Score	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	557
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Secondary: Change From Baseline in Presenteeism of WPAI-PSO

End point title	Change From Baseline in Presenteeism of WPAI-PSO

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	137[77]	243[78]	256[79]	242[80]
Units: Units on a Scale				
least squares mean (standard error)	-0.8 (± 1.37)	-16.4 (± 1.04)	-16.0 (± 1.01)	-18.1 (± 1.04)

Notes:

[77] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[78] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[79] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[80] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 7
Statistical analysis description: Presenteeism Score	
Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 8
Statistical analysis description: Presenteeism	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	393
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 9
Statistical analysis description: Presenteeism Score	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Secondary: Change From Baseline in Work Productivity Loss Score of WPAI-PSO

End point title	Change From Baseline in Work Productivity Loss Score of WPAI-PSO

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	50 mg Etanercept (ETN)	80 mg ixekizumab Dosing Regimen 2 (Q4W)	80 mg ixekizumab Dosing Regimen 1 (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	120[81]	216[82]	228[83]	216[84]
Units: Units on a Scale				
least squares mean (standard error)	0.6 (± 1.59)	-17.4 (± 1.20)	-16.7 (± 1.16)	-19.3 (± 1.19)

Notes:

[81] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[82] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[83] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[84] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 10

Statistical analysis description:

Work Productively Loss Score

Comparison groups	Placebo v 50 mg Etanercept (ETN)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 11

Statistical analysis description:

Work Productively Loss Score

Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W)
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 12
Statistical analysis description: Work Productively Loss Score	
Comparison groups	Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Induction, Long Term Extension and Follow-Up Periods	
Adverse event reporting additional description:	
I1F-MC-RHBC	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	50 mg Etanercept
Reporting group description: -	
Reporting group title	80 mg Ixekizumab Dosing Regimen 2 (Q4W)
Reporting group description: -	
Reporting group title	80 mg Ixekizumab Dosing Regimen 1 (Q2W)
Reporting group description: -	
Reporting group title	PBO/IXE80Q4W Long term extension
Reporting group description: -	
Reporting group title	ETN/IXE80Q4W Long term extension
Reporting group description: -	
Reporting group title	IXE80Q4W/IXE80Q4W Long term extension
Reporting group description: -	
Reporting group title	IXE80Q2W/IXE80Q4W Long term extension
Reporting group description: -	
Reporting group title	PBO follow-up period
Reporting group description: -	
Reporting group title	ETN follow-up period
Reporting group description: -	
Reporting group title	IXE80Q4W follow-up period
Reporting group description: -	
Reporting group title	IXE80Q2W follow-up period
Reporting group description: -	

Serious adverse events	Placebo	50 mg Etanercept	80 mg Ixekizumab Dosing Regimen 2 (Q4W)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 193 (2.59%)	8 / 382 (2.09%)	6 / 382 (1.57%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

basal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bone cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carcinoid tumour of the duodenum			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ewing's sarcoma metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (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
hodgkin's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease mixed cellularity stage unspecified			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to central nervous system			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to lung			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 137 (0.00%)	0 / 269 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 137 (0.00%)	0 / 269 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma stage ii			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial sarcoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 56 (0.00%)	1 / 113 (0.88%)	0 / 128 (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
vulval cancer metastatic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[5]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
air embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic vascular disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertensive crisis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture treatment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia repair			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hysterectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
implantable cardiac monitor insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perineal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyhydramnios			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
premature baby			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
accidental death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug withdrawal syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sarcoidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 137 (0.00%)	0 / 269 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
genital haemorrhage			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 56 (0.00%)	1 / 113 (0.88%)	0 / 128 (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
prostatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 137 (0.00%)	0 / 269 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine scar			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 56 (0.00%)	0 / 113 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung consolidation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal septum deviation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleurisy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
acute stress disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcohol abuse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar i disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
burnout syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hallucination			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

major depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biopsy liver			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
accident at work			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcohol poisoning			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
avulsion fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery restenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chemical burn of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	1 / 382 (0.26%)	0 / 382 (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
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incision site haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incisional hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (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
patella fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pelvic fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural bile leak			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seroma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subdural haematoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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 limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
laryngocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			

subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
angina pectoris			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bradycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral artery embolism			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

facial paralysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 cerebral infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic encephalopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lacunar infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
miller fisher syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paraesthesia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
reversible ischaemic neurological deficit			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
senile dementia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (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
conjunctivitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diplopia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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			
anal fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis microscopic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulum oesophageal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

haematemesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
intussusception			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis necrotising			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic function abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaundice cholestatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity vasculitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palmoplantar keratoderma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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 lesion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
calculus urinary			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (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
nephrotic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal artery arteriosclerosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cyst haemorrhage			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chondrocalcinosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee deformity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (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

osteonecrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
plica syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis perforated			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colonic abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic foot infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gas gangrene			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastroenteritis escherichia coli			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
liver abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mastoiditis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 137 (0.00%)	0 / 269 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pyelonephritis acute alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyonephrosis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	0 / 382 (0.00%)	0 / 382 (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
soft tissue infection alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal cord abscess alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
streptococcal sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
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 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	1 / 382 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic metabolic decompensation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperinsulinaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoglycaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 1 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	0 / 382 (0.00%)	0 / 382 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	80 mg Ixekizumab Dosing Regimen 1 (Q2W)	PBO/IXE80Q4W Long term extension	ETN/IXE80Q4W Long term extension
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 384 (2.34%)	45 / 183 (24.59%)	71 / 369 (19.24%)
number of deaths (all causes)	0	2	4
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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 lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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 neoplasm of thyroid gland			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bone cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carcinoid tumour of the duodenum			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ewing's sarcoma metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease mixed cellularity stage unspecified			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung cancer metastatic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
metastases to central nervous system			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to lung			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 130 (0.00%)	0 / 54 (0.00%)	1 / 109 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 254 (0.00%)	0 / 129 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 254 (0.00%)	0 / 129 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma stage ii			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial sarcoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
air embolism			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic vascular disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertensive crisis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

varicose vein			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture treatment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
gastric bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia repair			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hysterectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
implantable cardiac monitor insertion			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perineal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 130 (0.00%)	0 / 54 (0.00%)	1 / 109 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 130 (0.00%)	0 / 54 (0.00%)	1 / 109 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyhydramnios			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
premature baby			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
accidental death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest discomfort			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug withdrawal syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sarcoidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 254 (0.00%)	0 / 129 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
genital haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostatitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[12]	0 / 254 (0.00%)	0 / 129 (0.00%)	0 / 260 (0.00%)
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 scar			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 130 (0.00%)	0 / 54 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung consolidation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal polyps			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal septum deviation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	0 / 369 (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
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
pleurisy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
acute stress disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcohol abuse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
bipolar i disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
burnout syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
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 22.0			
subjects affected / exposed	1 / 384 (0.26%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hallucination			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biopsy liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
accident at work			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
alcohol poisoning			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
avulsion fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
carotid artery restenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chemical burn of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
clavicle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	2 / 183 (1.09%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incision site haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incisional hernia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
patella fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural bile leak			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

procedural pain alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seroma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
subdural haematoma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
tibia fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
laryngocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	3 / 369 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
bradycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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 failure acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

cardiac failure congestive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral artery embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
epilepsy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
facial paralysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic cerebral infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic encephalopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lacunar infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
miller fisher syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paraesthesia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
reversible ischaemic neurological deficit			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
senile dementia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
conjunctivitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diplopia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal vein thrombosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
anal fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
colitis microscopic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
diarrhoea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulum oesophageal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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

haemorrhoidal haemorrhage alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intussusception alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal haemorrhage alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine polyp alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis necrotising			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic function abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaundice cholestatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity vasculitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palmoplantar keratoderma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin lesion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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
skin ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
calculus urinary			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrotic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal artery arteriosclerosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cyst haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (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

ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chondrocalcinosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	2 / 183 (1.09%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee deformity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	4 / 369 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
plica syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis perforated			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast abscess			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	3 / 183 (1.64%)	4 / 369 (1.08%)
occurrences causally related to treatment / all	0 / 0	3 / 3	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

chronic tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colonic abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic foot infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	3 / 183 (1.64%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gas gangrene			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis escherichia coli			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
liver abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
mastoiditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 254 (0.00%)	0 / 129 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis acute			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
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 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyonephrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal cord abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
streptococcal sepsis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
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 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	3 / 369 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
diabetic metabolic decompensation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
hyperinsulinaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoglycaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	1 / 369 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 1 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 384 (0.00%)	1 / 183 (0.55%)	0 / 369 (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
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	2 / 369 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	0 / 183 (0.00%)	0 / 369 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IXE80Q4W/IXE80Q4W Long term extension	IXE80Q2W/IXE80Q4W Long term extension	PBO follow-up period
Total subjects affected by serious adverse events			
subjects affected / exposed	82 / 360 (22.78%)	55 / 362 (15.19%)	5 / 157 (3.18%)
number of deaths (all causes)	2	3	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
benign lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bone cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
carcinoid tumour of the duodenum			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
ewing's sarcoma metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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

hepatic adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
hodgkin's disease mixed cellularity stage unspecified			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
invasive breast carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
lung cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to central nervous system			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
metastases to lung			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 119 (0.00%)	0 / 121 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	2 / 241 (0.83%)	2 / 241 (0.83%)	0 / 108 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	1 / 241 (0.41%)	0 / 241 (0.00%)	0 / 108 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma stage ii			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
synovial sarcoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 119 (0.00%)	1 / 121 (0.83%)	0 / 49 (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
vulval cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	1 / 119 (0.84%)	0 / 121 (0.00%)	0 / 49 (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
Vascular disorders			
air embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	2 / 362 (0.55%)	0 / 157 (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
diabetic vascular disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	1 / 362 (0.28%)	0 / 157 (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
hypertensive crisis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
varicose vein			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
fracture treatment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia repair			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hysterectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	1 / 119 (0.84%)	0 / 121 (0.00%)	0 / 49 (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
implantable cardiac monitor insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perineal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 119 (0.00%)	0 / 121 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	2 / 119 (1.68%)	0 / 121 (0.00%)	0 / 49 (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
polyhydramnios			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 119 (0.00%)	0 / 121 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
premature baby			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
accidental death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
chest discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
drug withdrawal syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
sarcoidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[10]	0 / 241 (0.00%)	0 / 241 (0.00%)	0 / 108 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
genital haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 119 (0.00%)	0 / 121 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 241 (0.00%)	0 / 241 (0.00%)	0 / 108 (0.00%)
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 scar			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 119 (0.00%)	1 / 121 (0.83%)	0 / 49 (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 failure			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
hypoxia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
lung consolidation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
nasal polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
nasal septum deviation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleurisy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
acute stress disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
alcohol abuse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar i disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
burnout syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	2 / 362 (0.55%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hallucination			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
major depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
biopsy liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
glomerular filtration rate decreased			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
accident at work			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
alcohol poisoning			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
avulsion fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery restenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
chemical burn of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	3 / 362 (0.83%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	1 / 362 (0.28%)	0 / 157 (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
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incision site haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
incisional hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
lower limb fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 360 (0.83%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
patella fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
post procedural bile leak			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	2 / 362 (0.55%)	0 / 157 (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

seroma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
skull fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subdural haematoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
Congenital, familial and genetic disorders			
laryngocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
angina pectoris			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
angina unstable			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	2 / 362 (0.55%)	0 / 157 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
bradycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	1 / 362 (0.28%)	0 / 157 (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
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 360 (0.83%)	2 / 362 (0.55%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
myocarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
palpitations			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral artery embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
embolic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial paralysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 cerebral infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
hemiparesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
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 encephalopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lacunar infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
miller fisher syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
paraesthesia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
reversible ischaemic neurological deficit			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
senile dementia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
Eye disorders			
cataract			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
conjunctivitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
diplopia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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			
anal fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
colitis microscopic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	2 / 362 (0.55%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulum oesophageal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
intussusception			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis necrotising			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
umbilical hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 360 (1.11%)	4 / 362 (1.10%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
hepatic function abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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

jaundice cholestatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity vasculitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palmoplantar keratoderma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin lesion			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
calculus urinary			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
nephrotic syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 artery arteriosclerosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cyst haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
chondrocalcinosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
knee deformity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 360 (1.11%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
plica syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
spondylolisthesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 360 (0.83%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
appendicitis perforated			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
breast abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
campylobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 360 (0.83%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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 sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
colonic abscess			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
device related infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
diabetic foot infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
escherichia sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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

gas gangrene alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis escherichia coli alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
groin abscess alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infection alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
liver abscess alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mastoiditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
orchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	1 / 241 (0.41%)	0 / 241 (0.00%)	0 / 108 (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
osteomyelitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 22.0			
subjects affected / exposed	3 / 360 (0.83%)	1 / 362 (0.28%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	1 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pulmonary tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
pyelonephritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
pyelonephritis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyonephrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
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 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 360 (0.56%)	0 / 362 (0.00%)	0 / 157 (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
skin bacterial infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal cord abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
staphylococcal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
streptococcal sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
tooth abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (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
urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
urosepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
diabetic metabolic decompensation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperinsulinaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
hypoglycaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 360 (0.28%)	0 / 362 (0.00%)	0 / 157 (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
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 1 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	0 / 362 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 360 (0.00%)	1 / 362 (0.28%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ETN follow-up period	IXE80Q4W follow-up period	IXE80Q2W follow-up period
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 309 (1.62%)	2 / 305 (0.66%)	6 / 313 (1.92%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bone cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carcinoid tumour of the duodenum			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ewing's sarcoma metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hodgkin's disease mixed cellularity stage unspecified			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to central nervous system			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to lung			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 217 (0.00%)	0 / 205 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

prostate cancer metastatic alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 217 (0.00%)	0 / 205 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenoma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma stage ii alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial sarcoma alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 leiomyoma alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[4]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval cancer metastatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
air embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic vascular disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertensive crisis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture treatment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric bypass			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia repair			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hysterectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
implantable cardiac monitor insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perineal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	1 / 92 (1.09%)	0 / 100 (0.00%)	0 / 104 (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
polyhydramnios			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[9]	0 / 92 (0.00%)	1 / 100 (1.00%)	0 / 104 (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
premature baby			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	0 / 313 (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
General disorders and administration site conditions			
accidental death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug withdrawal syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sarcoidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 217 (0.00%)	0 / 205 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
genital haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 217 (0.00%)	0 / 205 (0.00%)	0 / 209 (0.00%)
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 scar			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 92 (0.00%)	0 / 100 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung consolidation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal septum deviation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pleurisy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary oedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
acute stress disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcohol abuse			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar i disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bipolar disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
burnout syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hallucination			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biopsy liver			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
accident at work			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcohol poisoning			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
avulsion fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery restenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chemical burn of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

clavicle fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incision site haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incisional hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

patella fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural bile leak			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seroma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subdural haematoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
laryngocele			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bradycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocarditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral artery embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	0 / 305 (0.00%)	0 / 313 (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
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	0 / 305 (0.00%)	0 / 313 (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
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial paralysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 cerebral infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic encephalopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lacunar infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
miller fisher syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paraesthesia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
reversible ischaemic neurological deficit			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
senile dementia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
conjunctivitis allergic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diplopia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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			
anal fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis microscopic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	0 / 313 (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
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulum oesophageal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric polyps			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intussusception			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pancreatitis necrotising			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaundice cholestatic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity vasculitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palmoplantar keratoderma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 309 (0.65%)	0 / 305 (0.00%)	0 / 313 (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
skin lesion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin ulcer			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
calculus urinary			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrotic syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal artery arteriosclerosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cyst haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chondrocalcinosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee deformity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
plica syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal abscess			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis perforated			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colonic abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic foot infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gas gangrene			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastroenteritis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis escherichia coli alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infection alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
liver abscess alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mastoiditis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 217 (0.00%)	0 / 205 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pyelonephritis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyonephrosis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal cord abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
streptococcal sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
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 22.0			
subjects affected / exposed	1 / 309 (0.32%)	0 / 305 (0.00%)	0 / 313 (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
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic metabolic decompensation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperinsulinaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoglycaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 1 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

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

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

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

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

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

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

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

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

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

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

[11] - 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 and female subjects. The number of subjects exposed has been adjusted accordingly.

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

[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification:

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

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

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

Non-serious adverse events	Placebo	50 mg Etanercept	80 mg Ixekizumab Dosing Regimen 2 (Q4W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 193 (20.73%)	90 / 382 (23.56%)	115 / 382 (30.10%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 193 (1.04%)	9 / 382 (2.36%)	3 / 382 (0.79%)
occurrences (all)	2	9	3
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 193 (2.59%)	11 / 382 (2.88%)	16 / 382 (4.19%)
occurrences (all)	10	15	23
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 193 (1.55%)	42 / 382 (10.99%)	43 / 382 (11.26%)
occurrences (all)	21	207	99
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 193 (1.04%)	6 / 382 (1.57%)	3 / 382 (0.79%)
occurrences (all)	2	6	7
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	4 / 382 (1.05%)	9 / 382 (2.36%)
occurrences (all)	0	4	10
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 193 (1.55%)	2 / 382 (0.52%)	6 / 382 (1.57%)
occurrences (all)	3	2	8
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	4 / 382 (1.05%)	8 / 382 (2.09%)
occurrences (all)	1	4	9
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 193 (1.55%)	0 / 382 (0.00%)	5 / 382 (1.31%)
occurrences (all)	3	0	6
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 193 (2.07%)	7 / 382 (1.83%)	9 / 382 (2.36%)
occurrences (all)	5	7	9
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 193 (1.04%)	2 / 382 (0.52%)	8 / 382 (2.09%)
occurrences (all)	2	3	8
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	4 / 382 (1.05%)	6 / 382 (1.57%)
occurrences (all)	0	4	6
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	2 / 382 (0.52%)	2 / 382 (0.52%)
occurrences (all)	0	2	2
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	1 / 382 (0.26%)	1 / 382 (0.26%)
occurrences (all)	0	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	11 / 193 (5.70%)	19 / 382 (4.97%)	29 / 382 (7.59%)
occurrences (all)	12	22	29
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 193 (0.52%)	2 / 382 (0.52%)	7 / 382 (1.83%)
occurrences (all)	1	2	7
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 193 (1.04%)	1 / 382 (0.26%)	1 / 382 (0.26%)
occurrences (all)	2	1	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 193 (2.59%)	8 / 382 (2.09%)	8 / 382 (2.09%)
occurrences (all)	5	8	8
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 193 (0.00%)	3 / 382 (0.79%)	5 / 382 (1.31%)
occurrences (all)	0	3	5
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[15]	1 / 56 (1.79%)	1 / 113 (0.88%)	1 / 128 (0.78%)
occurrences (all)	1	1	1

Non-serious adverse events	80 mg Ixekizumab Dosing Regimen 1 (Q2W)	PBO/IXE80Q4W Long term extension	ETN/IXE80Q4W Long term extension
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 384 (32.03%)	117 / 183 (63.93%)	240 / 369 (65.04%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 384 (1.30%)	20 / 183 (10.93%)	30 / 369 (8.13%)
occurrences (all)	6	24	42
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	16 / 384 (4.17%)	9 / 183 (4.92%)	30 / 369 (8.13%)
occurrences (all)	20	15	47
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	37 / 384 (9.64%)	18 / 183 (9.84%)	24 / 369 (6.50%)
occurrences (all)	111	102	186
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	11 / 384 (2.86%)	10 / 183 (5.46%)	27 / 369 (7.32%)
occurrences (all)	12	12	29
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 384 (1.56%)	11 / 183 (6.01%)	23 / 369 (6.23%)
occurrences (all)	6	17	29
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 384 (1.04%)	10 / 183 (5.46%)	16 / 369 (4.34%)
occurrences (all)	4	16	16
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 384 (1.82%)	2 / 183 (1.09%)	20 / 369 (5.42%)
occurrences (all)	9	2	25
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 384 (1.30%)	12 / 183 (6.56%)	17 / 369 (4.61%)
occurrences (all)	5	14	22
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	13 / 384 (3.39%)	17 / 183 (9.29%)	20 / 369 (5.42%)
occurrences (all)	14	17	24
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 384 (1.82%)	16 / 183 (8.74%)	28 / 369 (7.59%)
occurrences (all)	8	19	32
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 384 (0.26%)	17 / 183 (9.29%)	20 / 369 (5.42%)
occurrences (all)	1	24	23
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 384 (0.78%)	12 / 183 (6.56%)	12 / 369 (3.25%)
occurrences (all)	3	16	13
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 384 (0.78%)	11 / 183 (6.01%)	20 / 369 (5.42%)
occurrences (all)	3	16	20
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	26 / 384 (6.77%)	55 / 183 (30.05%)	104 / 369 (28.18%)
occurrences (all)	31	124	196
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 384 (0.00%)	4 / 183 (2.19%)	20 / 369 (5.42%)
occurrences (all)	0	6	26
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 384 (1.04%)	16 / 183 (8.74%)	10 / 369 (2.71%)
occurrences (all)	4	22	11
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	8 / 384 (2.08%)	21 / 183 (11.48%)	33 / 369 (8.94%)
occurrences (all)	8	27	58
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 384 (1.30%)	6 / 183 (3.28%)	18 / 369 (4.88%)
occurrences (all)	5	9	26
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[15]	1 / 130 (0.77%)	2 / 54 (3.70%)	2 / 109 (1.83%)
occurrences (all)	1	3	3

Non-serious adverse events	IXE80Q4W/IXE80Q4W Long term extension	IXE80Q2W/IXE80Q4W Long term extension	PBO follow-up period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	236 / 360 (65.56%)	249 / 362 (68.78%)	9 / 157 (5.73%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	30 / 360 (8.33%)	26 / 362 (7.18%)	1 / 157 (0.64%)
occurrences (all)	31	31	1
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	23 / 360 (6.39%)	27 / 362 (7.46%)	0 / 157 (0.00%)
occurrences (all)	27	39	0
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	34 / 360 (9.44%)	24 / 362 (6.63%)	0 / 157 (0.00%)
occurrences (all)	291	169	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	14 / 360 (3.89%)	25 / 362 (6.91%)	0 / 157 (0.00%)
occurrences (all)	18	32	0
Respiratory, thoracic and mediastinal disorders			

cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	14 / 360 (3.89%)	26 / 362 (7.18%)	0 / 157 (0.00%)
occurrences (all)	18	29	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	14 / 360 (3.89%)	16 / 362 (4.42%)	0 / 157 (0.00%)
occurrences (all)	18	20	0
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 360 (4.72%)	10 / 362 (2.76%)	0 / 157 (0.00%)
occurrences (all)	22	10	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 360 (4.72%)	15 / 362 (4.14%)	3 / 157 (1.91%)
occurrences (all)	28	17	3
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	29 / 360 (8.06%)	41 / 362 (11.33%)	0 / 157 (0.00%)
occurrences (all)	38	60	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	23 / 360 (6.39%)	30 / 362 (8.29%)	1 / 157 (0.64%)
occurrences (all)	33	34	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	24 / 360 (6.67%)	36 / 362 (9.94%)	0 / 157 (0.00%)
occurrences (all)	32	47	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 360 (1.39%)	18 / 362 (4.97%)	0 / 157 (0.00%)
occurrences (all)	5	18	0

influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	21 / 360 (5.83%)	20 / 362 (5.52%)	0 / 157 (0.00%)
occurrences (all)	23	21	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	107 / 360 (29.72%)	112 / 362 (30.94%)	4 / 157 (2.55%)
occurrences (all)	239	222	4
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 360 (4.72%)	21 / 362 (5.80%)	0 / 157 (0.00%)
occurrences (all)	20	23	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	28 / 360 (7.78%)	27 / 362 (7.46%)	0 / 157 (0.00%)
occurrences (all)	41	47	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	48 / 360 (13.33%)	42 / 362 (11.60%)	0 / 157 (0.00%)
occurrences (all)	67	68	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	21 / 360 (5.83%)	21 / 362 (5.80%)	0 / 157 (0.00%)
occurrences (all)	25	39	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[15]	6 / 119 (5.04%)	4 / 121 (3.31%)	0 / 49 (0.00%)
occurrences (all)	13	5	0

Non-serious adverse events	ETN follow-up period	IXE80Q4W follow-up period	IXE80Q2W follow-up period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 309 (7.44%)	14 / 305 (4.59%)	15 / 313 (4.79%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 309 (0.65%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 309 (0.65%)	1 / 305 (0.33%)	2 / 313 (0.64%)
occurrences (all)	2	1	2
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	0 / 313 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	10 / 309 (3.24%)	1 / 305 (0.33%)	4 / 313 (1.28%)
occurrences (all)	10	1	4

Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	1 / 305 (0.33%)	1 / 313 (0.32%)
occurrences (all)	1	1	1
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	1 / 305 (0.33%)	3 / 313 (0.96%)
occurrences (all)	0	1	3
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	0 / 313 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences (all)	1	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 309 (1.29%)	5 / 305 (1.64%)	2 / 313 (0.64%)
occurrences (all)	4	5	2
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 309 (0.00%)	0 / 305 (0.00%)	1 / 313 (0.32%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	1 / 305 (0.33%)	1 / 313 (0.32%)
occurrences (all)	1	1	1
upper respiratory tract infection			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	1 / 305 (0.33%)	2 / 313 (0.64%)
occurrences (all)	2	1	2
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 309 (0.32%)	3 / 305 (0.98%)	0 / 313 (0.00%)
occurrences (all)	1	3	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[15]	0 / 92 (0.00%)	1 / 100 (1.00%)	0 / 104 (0.00%)
occurrences (all)	0	1	0

Notes:

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2012	Changes to protocol (a): -Included monthly urine pregnancy testing for women of childbearing potential. -Removed evaluation of joint pain as a secondary objective. -Clarified use of concomitant topical products in the enrollment criteria. -Defined protocol criteria for premedication -Revised the primary analyses for categorical efficacy outcomes to a Cochran-Mantel-Haenszel (CMH) test stratified by center. -Used an MMRM approach for the primary analysis of continuous variables. -Added new details to more clearly define participants with moderate-to-severe heart failure and specified that these participants are excluded. -Revised an enrollment criterion to exclude participants positive for hepatitis B surface antigen or core antibody, regardless of their anti-hepatitis B surface antibody status. -Added a new exclusion and discontinuation criteria to exclude participants who have a condition/contradiction as addressed in local labeling for etanercept. -Revised the hepatic discontinuation rules. -Added a discontinuation rule for participants who develop symptoms suggestive of lupus-like syndrome and are positive for antibodies against double-stranded DNA. -Corrected treatment window for missed doses.
05 November 2012	Changes to protocol (b): -Non-inferiority analysis will be reported on both sPGA (0,1) and PASI 75 at Week 12 (non-responder imputation [NRI]) using a fixed margin approach. -The non-inferiority analysis will also be conducted using a US-only population. - The sPGA (0,1) and PASI 75 for the assessment of non-inferiority and superiority of ixekizumab to etanercept have been reordered. - The effect of center on the co-primary endpoints, sPGA (0,1) and PASI 75, will also be investigated based on the actual centers. - Additional details were added regarding the MMRM analysis. - Modified exclusion criterion to allow enrollment of participants who have had previous infection with hepatitis B virus (HBV) with conditions. - Added discontinuation requirement for positive HBV DNA test results. - Updated Study Schedule for hepatitis B monitoring. - Corrected inclusion criterion to require use of spermicide in conjunction with a diaphragm. - Clarified exclusion criterion to more clearly define participants with serious cardiac conditions - Clarified description of appropriate premedication. - Clarified the requirements for rescreening participants for tuberculosis. - Removed DNA collection at Week 24. -PASI 75 assumption for etanercept at Week 12 updated to 53%.
27 February 2015	Changes to protocol (c): -Modified major secondary objective for Itch to assess the proportion of participants achieving an Itch NRS ≥4 point reduction from baseline for participants who had baseline Itch NRS ≥4. -Added language to allow dosing to be increased to 80 mg ixekizumab Q2W after Week 60 during the Long-Term Extension Period (Period 3). -Modified discontinuation criteria. -Modified permitted concomitant medications. -Added language regarding collection of data on cerebrocardiovascular events for adjudication. -Updated hepatic discontinuation criteria. -Updated protocol-specified liver test criteria.

28 March 2017	Changes to protocol (d): -Added Crohn’s disease and ulcerative colitis adjudication. -Added clarity on dosing windows for Long-Term Extension Period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported