Clinical trial results:
A Multicenter Study with a Randomized, Double-Blind, Placebo-Controlled Induction Dosing Period Followed by a Randomized Maintenance Dosing Period and a Long-Term Extension Period to Evaluate the Efficacy and Safety of LY2439821 in Patients with Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2011-002970-22
Trial protocol	DE GB HU PL IT DK
Global end of trial date	20 September 2018

Results information

Result version number	v1 (current)
This version publication date	04 October 2019
First version publication date	04 October 2019

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHAZ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01474512
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12972

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	20 September 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 September 2018
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 LY2439821 compared to 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	16 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 212
Country: Number of subjects enrolled	Romania: 13
Country: Number of subjects enrolled	Hungary: 66
Country: Number of subjects enrolled	United States: 461
Country: Number of subjects enrolled	Japan: 33
Country: Number of subjects enrolled	Denmark: 16
Country: Number of subjects enrolled	Poland: 139
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	Australia: 42
Country: Number of subjects enrolled	Germany: 287
Worldwide total number of subjects	1296
EEA total number of subjects	548

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	1201
From 65 to 84 years	94
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Induction Period (Week 0 to 12), Maintenance Period (Week 12 to 60); Long term Extension (Week 60 to 264) and Post treatment (last treatment visit (week 264), or Early Termination Visit (ETV) up to a minimum of 12 weeks following that visit.

Pre-assignment

Screening details:

Participants received Ixekizumab (ixe) as responders (Resp, sPGA 0/1) in Induction (IND) re-randomized to receive ixe Q4W, Q12W or placebo (PBO) in Maintenance (MAIN) [Primary Population (Pop)]. In MAIN, non-responders (Non-Resp, sPGA >1) in IND received ixe Q4W, PBO Resp in IND received PBO (Secondary Pop). Ixe or PBO continued to end of study.

Period 1

Period 1 title	Induction Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo- Induction Period

Arm description:

Placebo was administered as 2 subcutaneous (SC) injections at week 0 then 1 PBO (SC) injection every 2 weeks (Q2W) up to Week 10.

Arm type	Experimental
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 was administered as 2 subcutaneous (SC) injections at week 0 then 1 PBO (SC) injection every 2 weeks (Q2W) up to Week 10.

Arm title	Ixe Q4W Induction Period

Arm description:

160 milligrams (mg) ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10.

Arm type	Experimental
Investigational medicinal product name	Ixe Q4W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160 milligrams (mg) ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10.

Arm title	Ixe Q2W - Induction Period

Arm description:

160 mg ixe administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection Q2W at Weeks 2, 4, 6, 8, and 10.

Arm type	Experimental
Investigational medicinal product name	Ixe Q2W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160 mg ixe administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection Q2W at Weeks 2, 4, 6, 8, and 10.

Number of subjects in period 1	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period
Started	431	432	433
Received Study Drug	431	432	433
Completed	407	408	415
Not completed	24	24	18
Consent withdrawn by subject	6	6	5
Adverse event, non-fatal	6	10	10
Sponsor Decision	1	1	1
Lost to follow-up	1	-	2
Lack of efficacy	7	1	-
Protocol deviation	3	6	-

Period 2

Period 2 title	Maintenance Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Subject, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	Ixe/Placebo- Maintenance Period Primary Pop

Arm description:

Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.

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 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.

Arm title	Ixe/Ixe Q12W - Maintenance Period Primary Pop

Arm description:

Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56. Pbo injection was given in between doses Q4W to maintain blindness.

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 or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56.

Arm title	Ixe/Ixe Q4W - Maintenance Period Primary Pop

Arm description:

Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

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 or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Arm title	Placebo Resp/Placebo - Maintenance Period Secondary Pop

Arm description:

Participants who received Placebo during the Induction Period (Weeks 0 to 10) and classified as responders and were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.

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 Placebo during the Induction Period (Weeks 0 to 10) and classified as responders and were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.

Arm title	Placebo Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop

Arm description:

Participants who received placebo in Induction Period (Weeks 0 to 10) and classified as non-responders

were administered 160 mg ixe as 2 SC injections at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

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 placebo in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 160 mg ixe as 2 SC injections at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Arm title	Ixe Q4W Non-Resp/Ixe Q4W- Maintenance Period Secondary Pop

Arm description:

Participants who received 80 mg ixe Q4W in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

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 Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Arm title	Ixe Q2W Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop

Arm description:

Participants who received 80 mg ixe Q2W in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

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 Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Arm title	Ixe Q4W - Maintenance Period Relapsed Population

Arm description:

Participants who relapsed during maintenance period prior to long term received, Ixe 80 mg as 1 SC injection Q4W for the remainder of the study to evaluate whether the response observed earlier could be regained on treatment with a higher dose.

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 relapsed during maintenance period prior to long term received, Ixe 80 mg as 1 SC injection Q4W for the remainder of the study to evaluate whether the response observed earlier could be regained on treatment with a higher dose.

Number of subjects in period 2	Ixe/Placebo-Maintenance Period Primary Pop	Ixe/Ixe Q12W - Maintenance Period Primary Pop	Ixe/Ixe Q4W - Maintenance Period Primary Pop
Started	226	227	229
Received Study Drug	226	227	229
Relapsed Population Received Drug	0 [1]	0 [2]	0 [3]
Relapsed Population Completers	0 [4]	0 [5]	0 [6]
Completed	24	108	177
Not completed	202	119	52
Adverse event, serious fatal	-	-	2
Consent withdrawn by subject	6	2	3
Physician decision	-	-	1
Clinical Relapse	1	-	-
Adverse event, non-fatal	4	2	7
Investigator Decision	-	-	-
Treated but Discontinued in Induction	-	1	-
Lost to follow-up	3	3	-
Relapsed (sPGA ≥3)	186	111	39
Lack of efficacy	1	-	-
Protocol deviation	1	-	-

Number of subjects in period 2	Placebo Resp/Placebo - Maintenance Period Secondary Pop	Placebo Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop	Ixe Q4W Non-Resp/Ixe Q4W- Maintenance Period Secondary Pop
Started	16	391	78
Received Study Drug	16	391	78
Relapsed Population Received Drug	0 [7]	0 [8]	0 [9]
Relapsed Population Completers	0 [10]	0 [11]	0 [12]
Completed	6	350	62
Not completed	10	41	16
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	6	3
Physician decision	-	-	-
Clinical Relapse	-	-	-

Adverse event, non-fatal	-	19	1
Investigator Decision	-	2	-
Treated but Discontinued in Induction	-	-	-
Lost to follow-up	-	2	1
Relapsed (sPGA ≥3)	9	-	-
Lack of efficacy	-	11	11
Protocol deviation	-	1	-

Number of subjects in period 2	Ixe Q2W Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop	Ixe Q4W - Maintenance Period Relapsed Population
Started	62	348
Received Study Drug	62	348
Relapsed Population Received Drug	0 [13]	348
Relapsed Population Completers	0 [14]	321
Completed	44	321
Not completed	18	27
Adverse event, serious fatal	-	-
Consent withdrawn by subject	1	4
Physician decision	-	1
Clinical Relapse	-	1
Adverse event, non-fatal	3	8
Investigator Decision	-	-
Treated but Discontinued in Induction	-	-
Lost to follow-up	1	5
Relapsed (sPGA ≥3)	-	-
Lack of efficacy	12	6
Protocol deviation	1	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants who received at least one dose of study drug are a subset to those who started the period.
[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants who received at least one dose of study drug are a subset to those who started the period.
[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants who received at least one dose of study drug are a subset to those who started the period.
[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

Period 3

Period 3 title	Long-Term Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Placebo Long-Term Extension

Arm description:

Participants who received placebo at the start of the long-term extension period and remained on placebo. Participants who received placebo at the start of long-term extension (Week 60) then switched to Ixe.

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:

PBO participants who switched to IXE or discontinued from the study at Week 60.

Arm title	Ixe Long-Term Extension

Arm description:

Participants who received 80 mg ixe in all dosing regimens at the start of the long-term extension period from Week 60 to Week 264.

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 in all dosing regimens at the start of the long-term extension period from Week 60 to Week 264.

Arm title	Total Ixe Long-Term Extension

Arm description:

Participants who received at least 1 dose of 80 mg ixe in all dosing regimens during the long-term extension period from Week 60 to Week 264, including those who have switched from PBO to Ixe in LTE 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 in all dosing regimens at the start of the long-term extension period from Week 60 to Week 264.

Number of subjects in period 3	Placebo Long-Term Extension	Ixe Long-Term Extension	Total Ixe Long-Term Extension
Started	26	1054	1075
Completed	0	836	855
Not completed	26	218	220
Adverse event, serious fatal	-	9	9
Parent/Caregiver Decision	-	1	1
Consent withdrawn by subject	3	61	61

Physician decision	-	21	21
Clinical Relapse	-	9	9
Adverse event, non-fatal	1	57	58
Sponsor Decision	-	6	6
Lost to follow-up	-	25	25
Switched From PBO to Ixe	21	-	-
Lack of efficacy	1	24	25
Protocol deviation	-	5	5

Period 4

Period 4 title	Post-Treatment Follow-Up
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Post-Treatment Follow-Up

Arm description:

Participants who received PBO prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

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 prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Arm title	Ixe Q12W Post-Treatment Follow-Up

Arm description:

Participants who received 80 mg ixe 1 SC injection Q12W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

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 1 SC injection Q12W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Arm title	Ixe Q4W Post-Treatment Follow-Up

Arm description:

Participants who received 80 mg ixe Q4W prior to entering the Post-Treatment Follow-Up period (a 12-

24 week period after their last scheduled treatment visit).

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 prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Arm title	Ixe Q2W Post-Treatment Follow-Up

Arm description:

Participants who received 80 mg ixe Q2W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

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 prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit.

Number of subjects in period 4[15]	Placebo Post-Treatment Follow-Up	Ixe Q12W Post-Treatment Follow-Up	Ixe Q4W Post-Treatment Follow-Up
Started	18	25	700
Completed	0	17	544
Not completed	18	8	156
Parent/Caregiver Decision	1	-	-
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	3	2	36
Physician decision	-	-	4
Clinical Relapse	-	-	6
Adverse event, non-fatal	8	2	58
Sponsor Decision	1	-	4
Lost to follow-up	-	-	12
Lack of efficacy	3	2	31
Protocol deviation	2	2	4

Number of subjects in period 4[15]	Ixe Q2W Post-Treatment Follow-Up
Started	285
Completed	239
Not completed	46

Parent/Caregiver Decision	1
Adverse event, serious fatal	-
Consent withdrawn by subject	17
Physician decision	5
Clinical Relapse	2
Adverse event, non-fatal	11
Sponsor Decision	-
Lost to follow-up	7
Lack of efficacy	3
Protocol deviation	-

Notes:

[15] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: All participants who received at least one dose of study drug are a subset to those who started the period.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo- Induction Period
Reporting group description:	
Placebo was administered as 2 subcutaneous (SC) injections at week 0 then 1 PBO (SC) injection every 2 weeks (Q2W) up to Week 10.	
Reporting group title	Ixe Q4W Induction Period
Reporting group description:	
160 milligrams (mg) ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10.	
Reporting group title	Ixe Q2W - Induction Period
Reporting group description:	
160 mg ixe administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection Q2W at Weeks 2, 4, 6, 8, and 10.	

Reporting group values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period
Number of subjects	431	432	433
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	46.4	45.6	45.1
standard deviation	± 13.40	± 12.95	± 12.40
Gender categorical Units: Subjects			
Female	128	143	142
Male	303	289	291
Region of Enrollment Units: Subjects			
Canada	77	69	66
Romania	8	3	2
Hungary	23	17	26
United States	146	156	159
Japan	13	12	8
Denmark	4	4	8
Poland	43	41	55
Italy	3	2	1
United Kingdom	7	7	7

Australia	19	15	8
Germany	88	106	93

Reporting group values	Total		
Number of subjects	1296		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	413		
Male	883		
Region of Enrollment Units: Subjects			
Canada	212		
Romania	13		
Hungary	66		
United States	461		
Japan	33		
Denmark	16		
Poland	139		
Italy	6		
United Kingdom	21		
Australia	42		
Germany	287		

End points

End points reporting groups

Reporting group title	Placebo- Induction Period
Reporting group description:	
Placebo was administered as 2 subcutaneous (SC) injections at week 0 then 1 PBO (SC) injection every 2 weeks (Q2W) up to Week 10.	
Reporting group title	Ixe Q4W Induction Period
Reporting group description:	
160 milligrams (mg) ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10.	
Reporting group title	Ixe Q2W - Induction Period
Reporting group description:	
160 mg ixe administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection Q2W at Weeks 2, 4, 6, 8, and 10.	
Reporting group title	Ixe/Placebo- Maintenance Period Primary Pop
Reporting group description:	
Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Ixe/Ixe Q12W - Maintenance Period Primary Pop
Reporting group description:	
Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56. Pbo injection was given in between doses Q4W to maintain blindness.	
Reporting group title	Ixe/Ixe Q4W - Maintenance Period Primary Pop
Reporting group description:	
Participants who received 80 mg ixe Q2W or Q4W in Induction Period (Weeks 0 to 10) and classified as responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Placebo Resp/Placebo - Maintenance Period Secondary Pop
Reporting group description:	
Participants who received Placebo during the Induction Period (Weeks 0 to 10) and classified as responders and were administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Placebo Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop
Reporting group description:	
Participants who received placebo in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 160 mg ixe as 2 SC injections at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Ixe Q4W Non-Resp/Ixe Q4W- Maintenance Period Secondary Pop
Reporting group description:	
Participants who received 80 mg ixe Q4W in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Ixe Q2W Non-Resp/Ixe Q4W - Maintenance Period Secondary Pop
Reporting group description:	
Participants who received 80 mg ixe Q2W in Induction Period (Weeks 0 to 10) and classified as non-responders were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.	
Reporting group title	Ixe Q4W - Maintenance Period Relapsed Population
Reporting group description:	
Participants who relapsed during maintenance period prior to long term received, Ixe 80 mg as 1 SC	

injection Q4W for the remainder of the study to evaluate whether the response observed earlier could be regained on treatment with a higher dose.

Reporting group title	Placebo Long-Term Extension

Reporting group description:

Participants who received placebo at the start of the long-term extension period and remained on placebo. Participants who received placebo at the start of long-term extension (Week 60) then switched to Ixe.

Reporting group title	Ixe Long-Term Extension

Reporting group description:

Participants who received 80 mg ixe in all dosing regimens at the start of the long-term extension period from Week 60 to Week 264.

Reporting group title	Total Ixe Long-Term Extension

Reporting group description:

Participants who received at least 1 dose of 80 mg ixe in all dosing regimens during the long-term extension period from Week 60 to Week 264, including those who have switched from PBO to Ixe in LTE period.

Reporting group title	Placebo Post-Treatment Follow-Up

Reporting group description:

Participants who received PBO prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	Ixe Q12W Post-Treatment Follow-Up

Reporting group description:

Participants who received 80 mg ixe 1 SC injection Q12W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	Ixe Q4W Post-Treatment Follow-Up

Reporting group description:

Participants who received 80 mg ixe Q4W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	Ixe Q2W Post-Treatment Follow-Up

Reporting group description:

Participants who received 80 mg ixe Q2W prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Subject analysis set title	Ixe/Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants who received ixe (Q2W or Q4W) in Induction Period who were re-randomized at Week 12 and administered placebo as 2 SC injections at Week 12 followed by placebo as 1 SC injection Q4W up to and including Week 56 (Maintenance Period).

Subject analysis set title	Ixe/Q12W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants who received ixe (Q2W or Q4W) in Induction Period who were re-randomized at Week 12 and were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q12W up to and including Week 56 (Maintenance Period).

Subject analysis set title	Ixe/Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants who received ixe (Q2W or Q4W) in Induction Period who were re-randomized at Week 12 and were administered 80 mg ixe as 1 SC injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56 (Maintenance Period).

Subject analysis set title	Ixe Q4W - Maintenance Period
Subject analysis set type	Per protocol

Subject analysis set description:

80 mg ixe administered as 1 SC injection Q4W from Week 12 up to Week 60

Subject analysis set title	Ixe Q12W - Maintenance Period
Subject analysis set type	Per protocol

Subject analysis set description:

80 mg ixe administered as 1 SC injection Q12W from Week 12 up to Week 60

Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants with Ctrough ss at specified timepoints.

Subject analysis set title	IxeQ4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants with Ctrough ss at specified timepoints

Primary: Percentage of Participants with static Physician Global Assessment (sPGA) of 0 or 1 (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: sPGA)

End point title	Percentage of Participants with static Physician Global Assessment (sPGA) of 0 or 1 (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: sPGA)

End point description:

The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participants Ps were assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	431[1]	432[2]	433[3]	
Units: percentage of participants				
number (not applicable)	3.2	76.4	81.8	

Notes:

[1] - All randomized participants or non-responders for Non-Responder Imputation (NRI) analysis.

[2] - All randomized participants or non-responders for Non-Responder Imputation (NRI) analysis.

[3] - All randomized participants or non-responders for Non-Responder Imputation (NRI) analysis.

Statistical analyses

Statistical analysis title	Percentage of Participants with Static Physician
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	863
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [4]
Method	Regression, Logistic

Confidence interval	
sides	2-sided

Notes:

[4] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors.

Statistical analysis title	Percentage of Participants with Static Physician
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	864
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [5]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[5] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors

Primary: Percentage of Participants achieving ≥75% Improvement in Ps Area and Severity Index (PASI75) (Efficacy of Ixekizumab in participants with moderate to severe plaque psoriasis Measure: PASI)

End point title	Percentage of Participants achieving ≥75% Improvement in Ps Area and Severity Index (PASI75) (Efficacy of Ixekizumab in participants with moderate to severe plaque psoriasis Measure: PASI)

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no Ps) to 72 (the most severe disease). Participants achieving PASI75 were defined as having an improvement of ≥75% in the PASI score compared to baseline.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	431[6]	432[7]	433[8]	
Units: percentage of participants				
number (not applicable)	3.9	82.6	89.1	

Notes:

[6] - All randomized participants and non-responders for NRI analysis.

[7] - All randomized participants and non-responders for NRI analysis.

[8] - All randomized participants and non-responders for NRI analysis.

Statistical analyses

Statistical analysis title	Percentage of Participants achieving ≥75% Improve
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	863
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [9]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[9] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors.

Statistical analysis title	Percentage of Participants achieving ≥75% Improve
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	864
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [10]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[10] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors.

Secondary: Percentage of Participants Achieving an sPGA of 0 (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: sPGA)

End point title	Percentage of Participants Achieving an sPGA of 0 (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: sPGA)

End point description:

The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participants Ps were assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe).

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	431[11]	432[12]	433[13]	
Units: percentage of participants				
number (not applicable)	0.0	34.5	37.0	

Notes:

[11] - All randomized participants and non-responders for NRI analysis.

[12] - All randomized participants and non-responders for NRI analysis.

[13] - All randomized participants and non-responders for NRI analysis.

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving an sPGA of 0
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	863
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [14]
Method	Fisher exact
Confidence interval	
sides	2-sided

Notes:

[14] - Due to the zero count in placebo group, p-values from Logistic Regression were not obtainable, therefore the p-value is from Fisher's exact test.

Statistical analysis title	Percentage of Participants Achieving an sPGA of 0
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	864
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [15]
Method	Fisher exact
Confidence interval	
sides	2-sided

Notes:

[15] - Due to the zero count in placebo group, p-values from Logistic Regression were not obtainable, therefore the p-value is from Fisher's exact test

Secondary: Percentage of Participants Achieving PASI 90% (PASI90) or 100% (PASI100) (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: PASI)

End point title	Percentage of Participants Achieving PASI 90% (PASI90) or 100% (PASI100) (Efficacy of Ixekizumab in participants with moderate to severe plaque Ps Measure: PASI)

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored by itself and the scores were then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no Ps) to 72 (the most severe disease). Participants achieving PASI90 or PASI100 were defined as having an improvement of ≥90% or of 100% respectively in PASI scores compared to baseline.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	431[16]	432[17]	433[18]	
Units: percentage of participants				
number (not applicable)				
PASI90	0.5	64.6	70.9	
PASI100	0.0	33.6	35.3	

Notes:

[16] - All randomized participants and non-responders for NRI analysis.

[17] - All randomized participants and non-responders for NRI analysis.

[18] - All randomized participants and non-responders for NRI analysis.

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving PASI 90%
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	863
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [19]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[19] - P-value is for PASI90.

Statistical analysis title	Percentage of Participants Achieving PASI 90%
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	864
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [20]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[20] - P-value is for PASI90.

Statistical analysis title	Percentage of Participants Achieving PASI 90%
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	863
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [21]
Method	Fisher exact

Confidence interval	
sides	2-sided

Notes:

[21] - P-value is for PASI100.

Statistical analysis title	Percentage of Participants Achieving PASI 90%
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	864
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [22]
Method	Fisher exact
Confidence interval	
sides	2-sided

Notes:

[22] - P-value is for PASI100.

Secondary: Percentage of participants maintaining sPGA 0 or 1 after Re-Randomization at start of maintenance dosing period

End point title	Percentage of participants maintaining sPGA 0 or 1 after Re-Randomization at start of maintenance dosing period

End point description:

The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participants Ps were assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe).

End point type	Secondary

End point timeframe:

Week 60

End point values	Ixe/Placebo-Maintenance Period Primary Pop	Ixe/Ixe Q12W - Maintenance Period Primary Pop	Ixe/Ixe Q4W - Maintenance Period Primary Pop	Ixe/Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	226[23]	227[24]	227[25]	226
Units: percentage of participants				
number (not applicable)	7.5	37.4	72.9	7.5

Notes:

[23] - All participants who received at least one dose of study drug and non-responders for NRI.

[24] - All participants who received at least one dose of study drug and non-responders for NRI.

[25] - All participants who received at least one dose of study drug and non-responders for NRI.

End point values	Ixe/Q12W	Ixe/Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	227	229		
Units: percentage of participants				
number (not applicable)	37.4	72.9		

Statistical analyses

Statistical analysis title	Percentage of participants maintaining sPGA 0 or 1
Comparison groups	Ixe/Placebo v Ixe/Q12W
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [26]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[26] - Logistic Regression analysis included treatment and baseline weight category as factors.

Statistical analysis title	Percentage of participants maintaining sPGA 0 or 1
Comparison groups	Ixe/Placebo v Ixe/Q4W
Number of subjects included in analysis	455
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [27]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[27] - Logistic Regression analysis included treatment and baseline weight category as factors.

Secondary: Percentage of Participants with Itch Numeric Rating Scale (Itch NRS) Score ≥4 Point reduction from baseline

End point title	Percentage of Participants with Itch Numeric Rating Scale (Itch NRS) Score ≥4 Point reduction from baseline

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 (no itch) and 10 (worst itch imaginable). Overall severity of a participant's itching from Ps is indicated by circling the number that best describes the worst level of itching in the past 24 hours.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	374[28]	379[29]	391[30]	
Units: percentage of participants				
number (not applicable)	15.5	80.5	85.9	

Notes:

[28] - All randomized participants and non-responders for NRI analysis.

[29] - All randomized participants and non-responders for NRI analysis.

[30] - All randomized participants and non-responders for NRI analysis.

Statistical analyses

Statistical analysis title	Percentage of Participants with Itch
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	753
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [31]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[31] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors

Statistical analysis title	Percentage of Participants with Itch
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [32]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[32] - Logistic Regression analysis included treatment, geographic region, previous non-biologic systemic therapy and baseline weight category as factors

Secondary: Change from baseline in Dermatology-Specific Quality of Life Index (DLQI) Score

End point title	Change from baseline in Dermatology-Specific Quality of Life Index (DLQI) Score

End point description:

DLQI is a participant-administered, 10-question, validated, quality-of-life questionnaire that covers 6 domains, including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include 0 (not at all), 1 (a little), 2 (a lot), and 3 (very much) and unanswered ("not relevant") responses were scored as "0." Total scores range from 0 to 30, with higher score indicating greater quality of life is impairment. A 5-point change from baseline is considered clinically relevant. Least squares (LS) mean change from baseline was calculated using mixed model repeated measures (MMRM).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	421[33]	421[34]	427[35]	
Units: units on a scale				
least squares mean (standard error)	-1.0 (± 0.27)	-10.7 (± 0.27)	-11.1 (± 0.26)	

Notes:

[33] - All randomized participants and those who had at least 1 post baseline measurement.

[34] - All randomized participants and those who had at least 1 post baseline measurement.

[35] - All randomized participants and those who had at least 1 post baseline measurement.

Statistical analyses

Statistical analysis title	Change from baseline in DLQI Score
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	842
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [36]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[36] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Statistical analysis title	Change from baseline in DLQI Score
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	848
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [37]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[37] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

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

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

End point description:

The NAPSI is a numeric, reproducible, objective tool for evaluation of fingernail Ps. This scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix Ps 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 Ps 0 (none) to 4 (Ps in 4 quadrants of the fingernail) and fingernail matrix Ps 0 (none) to 4 (Ps in 4 quadrants of the matrix), depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed or matrix Ps 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, then the sum of all fingernails equals the total NAPSI score with a range from 0 to 80 with higher scores indicating more severe psoriasis. LS mean change from baseline was calculated using MMRM.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	280[38]	276[39]	279[40]	
Units: units on a scale				
least squares mean (standard error)	2.17 (± 0.672)	-7.19 (± 0.671)	-7.24 (± 0.657)	

Notes:

[38] - All randomized participants and those who had fingernail Ps at baseline.

[39] - All randomized participants and those who had fingernail Ps at baseline.

[40] - All randomized participants and those who had fingernail Ps at baseline.

Statistical analyses

Statistical analysis title	Change from baseline in NAPSI
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [41]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[41] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Statistical analysis title	Change from baseline in NAPSI
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	559
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [42]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[42] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Secondary: Percent of Body Surface Area (BSA) involvement of Ps

End point title	Percent of Body Surface Area (BSA) involvement of Ps

End point description:

BSA is a physician rating of the percentage of involvement of Ps for each participant. BSA is assessed on a continuous scale from 0% (no involvement) to 100% (full involvement), where 1% corresponds to the size of the participants hand (includes the palm, fingers and thumb). Total BSA is the sum of handprints from the affected areas. LS mean change from baseline was calculated using MMRM.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	426[43]	425[44]	428[45]	
Units: percentage of body surface				
least squares mean (standard error)	1.3 (± 0.67)	-21.4 (± 0.67)	-22.4 (± 0.66)	

Notes:

[43] - All randomized participants and those who had at least 1 post-baseline BSA measurement.

[44] - All randomized participants and those who had at least 1 post-baseline BSA measurement.

[45] - All randomized participants and those who had at least 1 post-baseline BSA measurement.

Statistical analyses

Statistical analysis title	Percent of Body Surface Area (BSA)
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	851
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [46]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[46] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Statistical analysis title	Percent of Body Surface Area (BSA)
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	854
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [47]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[47] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Secondary: Change from baseline in Psoriasis Scalp Severity Index (PSSI)

End point title	Change from baseline in Psoriasis Scalp Severity Index (PSSI)

End point description:

The PSSI is a physician assessment of erythema, induration and desquamation and percent of scalp that is covered with a scores range from 0 (none) to 4 (very severe). The composite score is derived from the sum of scores for erythema, induration, and desquamation multiplied by the score recorded for the extent of the scalp area involved, 1 (<10%) to 6 (90%-100%) with a total scores range from 0 to 72, with lower scores indicating less severity. LS mean change from baseline was calculated using MMRM.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	393[48]	413[49]	393[50]	
Units: units on a scale				
least squares mean (standard error)	-1.8 (± 0.53)	-18.3 (± 0.52)	-19.2 (± 0.52)	

Notes:

[48] - All randomized participants and those who had scalp Ps at baseline.

[49] - All randomized participants and those who had scalp Ps at baseline.

[50] - All randomized participants and those who had scalp Ps at baseline.

Statistical analyses

Statistical analysis title	Change from baseline in Psoriasis Scalp Severity
Comparison groups	Ixe Q4W Induction Period v Placebo- Induction Period
Number of subjects included in analysis	806
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [51]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[51] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Statistical analysis title	Change from baseline in Psoriasis Scalp Severity
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	786
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [52]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[52] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Secondary: Change from Baseline in all scores of the Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO) (Quality of life and outcome assessments. Measures: Participant Reported Outcomes [PRO])

End point title	Change from Baseline in all scores of the Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO) (Quality of life and outcome assessments. Measures: Participant Reported Outcomes [PRO])

End point description:

WPAI-PSO is a participant administered, 6-item instrument used to assess the impact of Ps on the productivity impairment within the past 7 days. WPAI-PSO has 4 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 (reduced productivity while at work), overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 with greater scores indicating greater impairment. LS mean change from baseline was calculated using analysis of covariance (ANCOVA).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	420[53]	417[54]	427[55]	
Units: units on a scale				
least squares mean (standard error)				
Absenteeism	0.2 (± 0.88)	-3.5 (± 0.87)	-2.6 (± 0.84)	
Activity Impairment	0.8 (± 1.18)	-24.5 (± 1.18)	-25.2 (± 1.15)	
Presenteeism	0.5 (± 1.30)	-18.8 (± 1.28)	-18.3 (± 1.24)	
Work Productivity Loss	-0.8 (± 1.40)	-20.6 (± 1.38)	-19.8 (± 1.33)	

Notes:

[53] - All randomized participants had results at specific timepoints, last observation carried forward.

[54] - All randomized participants had results at specific timepoints, last observation carried forward.

[55] - All randomized participants had results at specific timepoints, last observation carried forward.

Statistical analyses

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	837
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [56]
Method	ANCOVA

Confidence interval	
sides	2-sided

Notes:

[56] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	847
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.003 [57]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[57] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	837
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [58]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[58] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	847
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [59]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[59] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period

Number of subjects included in analysis	837
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [60]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[60] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	847
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [61]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[61] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	837
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [62]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[62] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Statistical analysis title	Change from Baseline in all scores of the WPAI-PSO
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	847
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [63]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[63] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline WPAI value.

Secondary: Change from Baseline in Quick Inventory of Depressive

Symptomatology-Self Reported 16 Items (QIDS-SR16)	
End point title	Change from Baseline in Quick Inventory of Depressive Symptomatology-Self Reported 16 Items (QIDS-SR16)

End point description:

QIDS-SR16 is a participant-administered, 16-item instrument intended to assess the existence and severity of symptoms of depression. A participant is asked to consider each statement as it relates to the way they have felt for the past 7 days and rate each on a 4-point scale: 0 (best) to 3 (worst). The sum of the 16 items corresponding to 9 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] to give a single total scores range from 0 to 27, with higher scores indicating greater symptom severity. LS mean change from baseline was calculated using ANCOVA.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	421[64]	417[65]	423[66]	
Units: units on a scale				
least squares mean (standard error)	-0.1 (± 0.17)	-1.0 (± 0.17)	-1.3 (± 0.17)	

Notes:

[64] - All randomized participants and those that had results at the specified time points, LOCF.

[65] - All randomized participants and those that had results at the specified time points, LOCF.

[66] - All randomized participants and those that had results at the specified time points, LOCF.

Statistical analyses

Statistical analysis title	Change from Baseline in QIDS-SR16
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	838
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [67]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[67] - LS Mean and p-values were calculated using an ANCOVA model that included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline QIDS value in the model.

Statistical analysis title	Change from Baseline in QIDS-SR16
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	844
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [68]
Method	ANCOVA

Confidence interval	
sides	2-sided

Notes:

[68] - LS Mean and p-values were calculated using an ANCOVA model that included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline QIDS value in the model.

Secondary: Change from baseline in Medical Outcomes Study 36-item short form health survey (SF-36) and physical component summary (PCS) and Mental component summary (MCS)

End point title	Change from baseline in Medical Outcomes Study 36-item short form health survey (SF-36) and physical component summary (PCS) and Mental component summary (MCS)

End point description:

The SF-36 is a self-reported instrument that measures the participant's health status during the previous 7 days. 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 in the PCS and MCS scores. Scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. LS mean change from baseline was calculated using ANCOVA.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	418[69]	415[70]	427[71]	
Units: units on a scale				
least squares mean (standard error)				
PCS	-0.1747 (± 0.4012)	4.3081 (± 0.3990)	4.3159 (± 0.3878)	
MCS	0.8729 (± 0.4638)	3.7386 (± 0.4633)	4.1293 (± 0.4480)	

Notes:

[69] - All randomized participants and those with results at the specified time points, LOCF.

[70] - All randomized participants and those with results at the specified time points, LOCF.

[71] - All randomized participants and those with results at the specified time points, LOCF.

Statistical analyses

Statistical analysis title	Change from baseline in SF-36
Comparison groups	Ixe Q4W Induction Period v Placebo- Induction Period
Number of subjects included in analysis	833
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [72]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[72] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline SF-36 value in the model.

Statistical analysis title	Change from baseline in SF-36
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	845
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [73]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[73] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline SF-36 value in the model.

Statistical analysis title	Change from baseline in SF-36
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	833
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [74]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[74] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline SF-36 value in the model.

Statistical analysis title	Change from baseline in SF-36
Comparison groups	Ixe Q2W - Induction Period v Placebo- Induction Period
Number of subjects included in analysis	845
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [75]
Method	ANCOVA
Confidence interval	
sides	2-sided

Notes:

[75] - The LS Mean and p-values were calculated using an ANCOVA model and included treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, and baseline SF-36 value in the model.

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 PatGA is a single-item self-reported instrument asking the participant to rate the severity of their psoriasis "today" by circling a number on the numeric rating scale from 0 (Clear = no psoriasis) to 5 (Severe = the worst their psoriasis has ever been). LS mean change from baseline calculated using MMRM.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	424[76]	425[77]	427[78]	
Units: units on a scale				
least squares mean (standard error)	-0.2 (± 0.06)	-3.1 (± 0.06)	-3.2 (± 0.06)	

Notes:

[76] - All randomized participants and those with at least 1 poste-baseline PatGA.

[77] - All randomized participants and those with at least 1 poste-baseline PatGA.

[78] - All randomized participants and those with at least 1 poste-baseline PatGA.

Statistical analyses

Statistical analysis title	Change from baseline in PatGA
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	851
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [79]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[79] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Statistical analysis title	Change from baseline in PatGA
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	849
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [80]
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Notes:

[80] - LS mean and P-value were calculated using MMRM with baseline score as a covariate, treatment, geographic region, previous non-biologic systemic therapy, baseline weight category, visit and treatment-by-visit interaction as fixed effects.

Secondary: Percentage of Participants achieving Palmoplantar PASI (PPASI) of ≥50% (PPASI50), ≥75% (PPASI75), or 100% (PPASI100) Improvement

End point title	Percentage of Participants achieving Palmoplantar PASI (PPASI) of ≥50% (PPASI50), ≥75% (PPASI75), or 100% (PPASI100) Improvement

End point description:

The Palmoplantar PASI is a composite score derived from the sum of scores for erythema, induration, and desquamation [scores range from 0 (none) to 4 (very severe) for each] multiplied by the score for the extent of palm and sole area involvement [scores range from 0 (0%) to 6 (90 to100%)], with a total scores range from 0 to 72. Participants achieving PPASI50, PPASI75 or PASI100 were defined as having an improvement of at least 50%, 90%, or of 100%, respectively, in the PPASI scores compared to baseline.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo- Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	133[81]	131[82]	140[83]	
Units: percentage of participants				
number (not applicable)				
PPASI50	35.3	84.0	82.9	
PPASI75	26.3	74.8	77.1	
PPASI100	20.3	65.6	70.0	

Notes:

[81] - All randomized participants and those who had palmoplantar Ps at baseline.

[82] - All randomized participants and those who had palmoplantar Ps at baseline.

[83] - All randomized participants and those who had palmoplantar Ps at baseline.

Statistical analyses

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Ixe Q4W Induction Period v Placebo- Induction Period
Number of subjects included in analysis	264
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [84]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[84] - P-value is for PPASI50.

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [85]
Method	Regression, Logistic

Confidence interval	
sides	2-sided

Notes:
[85] - P-value is for PPASI50.

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	264
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [86]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:
[86] - P-value is for PPASI75

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [87]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:
[87] - P-value is for PPASI75

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Placebo- Induction Period v Ixe Q4W Induction Period
Number of subjects included in analysis	264
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [88]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:
[88] - P-value is for PPASI100

Statistical analysis title	Percentage of Participants achieving PPASI
Comparison groups	Placebo- Induction Period v Ixe Q2W - Induction Period

Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [89]
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Notes:

[89] - P-value if for PPASI100.

Secondary: Pharmacokinetics (PK): Trough concentration at steady state (Ctrough ss)

End point title	Pharmacokinetics (PK): Trough concentration at steady state (Ctrough ss)

End point description:

End point type	Secondary

End point timeframe:

Weeks 12: Day 84 and Week 24: Day 168

End point values	Ixe Q4W - Maintenance Period	Ixe Q12W - Maintenance Period	Ixe Q2W	IxeQ4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	223[90]	60[91]	192[92]	215[93]
Units: micrograms/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Week 12	0 (± 0)	0 (± 0)	7.73 (± 79)	2.94 (± 89)
Week 24	2.36 (± 111)	0.281 (± 175)	0 (± 0)	0 (± 0)

Notes:

[90] - Geometric coefficient of variation is presented as a percent.

[91] - Geometric coefficient of variation is presented as a percent.

[92] - Geometric coefficient of variation is presented as a percent.

[93] - Geometric coefficient of variation is presented as a percent.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Anti-ixekizumab antibodies

End point title	Percentage of Participants with Anti-ixekizumab antibodies

End point description:

Percentage of participants with treatment-emergent positive anti-ixekizumab antibodies was summarized by treatment group. Percentage was calculated based on the number of evaluable participants and was calculated by number of participants with treatment-emergent positive anti-ixekizumab antibodies / number of evaluable participants * 100%.

End point type	Secondary

End point timeframe:

Baseline through Week 12

End point values	Placebo-Induction Period	Ixe Q4W Induction Period	Ixe Q2W - Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	431[94]	432[95]	433[96]	
Units: percentage of participants				
number (not applicable)	0.5	12.5	10.3	

Notes:

[94] - All randomized participants who received at least 1 dose of study drug and had evaluable data.

[95] - All randomized participants who received at least 1 dose of study drug and had evaluable data.

[96] - All randomized participants who received at least 1 dose of study drug and had evaluable data.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Induction, Maintenance Dosing, Long Term Extension and Follow-Up Periods

Adverse event reporting additional description:

I1F-MC-RHAZ

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	PBO-induction period
Reporting group description: -	
Reporting group title	IXE80Q4W-induction period
Reporting group description: -	
Reporting group title	IXE80Q2W-induction period
Reporting group description: -	
Reporting group title	IXE/PBO-maintenance primary population
Reporting group description: -	
Reporting group title	IXE/IXE80Q12W-maintenance primary population
Reporting group description: -	
Reporting group title	IXE/IXE80Q4W-maintenance primary population
Reporting group description: -	
Reporting group title	PBOResp/PBO-maintenance secondary population
Reporting group description: -	
Reporting group title	PBONonR/IXE80Q4W-maintenance secondary population
Reporting group description: -	
Reporting group title	IXE80Q4WNonR/IXE80Q4W-maintenance secondary population
Reporting group description: -	
Reporting group title	IXE80Q2WNonR/IXE80Q4W-maintenance secondary population
Reporting group description: -	
Reporting group title	IXE80Q4W-maintenance relapse population
Reporting group description: -	
Reporting group title	PBO-long term extension period
Reporting group description: -	
Reporting group title	IXE-long term extension period
Reporting group description: -	
Reporting group title	Total IXE-long term extension period
Reporting group description: -	
Reporting group title	PBO-follow-up period
Reporting group description: -	
Reporting group title	IXE80Q2W-follow-up period
Reporting group description: -	
Reporting group title	IXE80Q4W-follow-up period
Reporting group description: -	
Reporting group title	IXE80Q12W-follow-up period

Reporting group description: -

Serious adverse events	PBO-induction period	IXE80Q4W-induction period	IXE80Q2W-induction period
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 431 (1.16%)	12 / 432 (2.78%)	7 / 433 (1.62%)
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)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

diffuse large b-cell lymphoma alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypopharyngeal cancer alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (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
intraductal proliferative breast lesion alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 ductal breast carcinoma alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
laryngeal squamous cell carcinoma alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed[1]	0 / 303 (0.00%)	0 / 289 (0.00%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 hiatus repair			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed[2]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hellp syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
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			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
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 21.1			
subjects affected / exposed[7]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectocele			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed[8]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
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			
asthma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	1 / 431 (0.23%)	1 / 432 (0.23%)	0 / 433 (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
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 contusion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle rupture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 complication alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 compression fracture alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
angina pectoris			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
tinnitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
retinal detachment			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
retinal haemorrhage			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 ischaemic			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 haemorrhage alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 obstruction alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 relapsing alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 eruption			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (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
drug reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
bone pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exostosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis pharyngeal			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 128 (0.00%)	0 / 143 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 empyema			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 bacterial infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (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
injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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

laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (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
tooth abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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			
acidosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
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	IXE/PBO-maintenance primary population	IXE/IXE80Q12W-maintenance primary population	IXE/IXE80Q4W-maintenance primary population
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 226 (3.10%)	11 / 227 (4.85%)	14 / 229 (6.11%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypopharyngeal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 ductal breast carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed[1]	0 / 154 (0.00%)	0 / 150 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 hiatus repair			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed[2]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hellp syndrome			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed[3]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
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			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
drug withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
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 21.1			
subjects affected / exposed[7]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[8]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
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			
asthma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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 embolism			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug-induced liver injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 complication			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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 compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congenital pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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 pectoris			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cardiac failure congestive			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
coronary artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
palpitations			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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 infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
epilepsy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
tinnitus			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
retinal detachment			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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

diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 relapsing			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 eruption			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
renal colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
bone pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exostosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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 chest pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 pharyngeal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 72 (0.00%)	0 / 77 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 empyema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 bacterial infection			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
pneumonia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (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
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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			
acidosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
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 21.1			

subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (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	PBOResp/PBO-maintenance secondary population	PBONonR/IXE80Q4W-maintenance secondary population	IXE80Q4WNonR/IXE80Q4W-maintenance secondary population
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	24 / 391 (6.14%)	8 / 78 (10.26%)
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)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypopharyngeal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 ductal breast carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed[1]	0 / 10 (0.00%)	0 / 276 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 hiatus repair			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed[2]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hellp syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
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			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
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 21.1			

subjects affected / exposed[7]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[8]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
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			
asthma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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-induced liver injury			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 complication			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
angina pectoris			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	3 / 391 (0.77%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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

coronary artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
palpitations			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
tinnitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
retinal detachment			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
chronic gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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 obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 relapsing			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
drug eruption			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
nephrolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
bone pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exostosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	2 / 391 (0.51%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis pharyngeal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
ear infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 6 (0.00%)	0 / 115 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 empyema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 bacterial infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
staphylococcal osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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
subcutaneous abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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			
acidosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
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 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	0 / 78 (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	IXE80Q2WNonR/IXE80Q4W-maintenance secondary population	IXE80Q4W-maintenance relapse population	PBO-long term extension period
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 62 (4.84%)	11 / 348 (3.16%)	1 / 26 (3.85%)
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)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypopharyngeal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 ductal breast carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed[1]	0 / 41 (0.00%)	0 / 241 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 hiatus repair			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed[2]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hellp syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
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			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
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 21.1			
subjects affected / exposed[7]	0 / 21 (0.00%)	1 / 107 (0.93%)	0 / 11 (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
rectocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[8]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
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			
asthma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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-induced liver injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

muscle rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 complication			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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 pectoris			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
lacunar infarction			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
tinnitus			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 62 (1.61%)	0 / 348 (0.00%)	0 / 26 (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
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
retinal detachment			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	0 / 348 (0.00%)	0 / 26 (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
gastritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 relapsing			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 eruption			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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 colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
urinary incontinence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (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
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
bone pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exostosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 chest pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 pharyngeal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 21 (0.00%)	0 / 107 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 empyema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 bacterial infection			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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			
acidosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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 21.1			

subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
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	IXE-long term extension period	Total IXE-long term extension period	PBO-follow-up period
Total subjects affected by serious adverse events			
subjects affected / exposed	134 / 1054 (12.71%)	134 / 1075 (12.47%)	2 / 18 (11.11%)
number of deaths (all causes)	7	7	0
number of deaths resulting from adverse events	4	4	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
hypopharyngeal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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

lung cancer metastatic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	2 / 2	2 / 2	0 / 0
lung neoplasm malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
pituitary tumour benign			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
prostate cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[1]	1 / 731 (0.14%)	1 / 743 (0.13%)	0 / 13 (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
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
renal cell carcinoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	3 / 6	3 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
varicose vein			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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

Surgical and medical procedures			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 hiatus repair			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
varicose vein operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[2]	1 / 323 (0.31%)	1 / 332 (0.30%)	0 / 5 (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
hellp syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 323 (0.00%)	0 / 332 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 323 (0.00%)	0 / 332 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	1 / 323 (0.31%)	1 / 332 (0.30%)	0 / 5 (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
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	1 / 323 (0.31%)	1 / 332 (0.30%)	0 / 5 (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
ovarian cyst			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed[7]	2 / 323 (0.62%)	2 / 332 (0.60%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[8]	1 / 323 (0.31%)	1 / 332 (0.30%)	0 / 5 (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
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
pleurisy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Psychiatric disorders			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Hepatobiliary disorders			
bile duct stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
cholelithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Investigations			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
bone contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
fall			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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

limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
meniscus injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
muscle rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
post procedural complication			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
rib fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
road traffic accident			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
tibia fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
upper limb fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
angina pectoris			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
angina unstable			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

coronary artery occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	4 / 1054 (0.38%)	4 / 1075 (0.37%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palpitations			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
ischaemic stroke			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
lacunar infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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

multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
vascular encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
colitis ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis relapsing			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
umbilical hernia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 eruption			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
drug reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
urinary incontinence			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
bone pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
exostosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
intervertebral disc degeneration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 1054 (0.38%)	4 / 1075 (0.37%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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

rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
rotator cuff syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
spinal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
synovitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			

subjects affected / exposed	4 / 1054 (0.38%)	4 / 1075 (0.37%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	2 / 4	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis pharyngeal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
chronic tonsillitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
cystitis bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
device related infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
ear infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 323 (0.00%)	0 / 332 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder empyema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
gastrointestinal bacterial infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
lower respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
osteomyelitis chronic			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	5 / 1054 (0.47%)	5 / 1075 (0.47%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 5	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal osteomyelitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	2 / 5	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 1054 (0.19%)	2 / 1075 (0.19%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
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			
acidosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (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
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IXE80Q2W-follow-up period	IXE80Q4W-follow-up period	IXE80Q12W-follow-up period
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 285 (2.11%)	13 / 700 (1.86%)	0 / 25 (0.00%)
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)			
adrenal adenoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangiocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
colon cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypopharyngeal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 ductal breast carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 malignant			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed[1]	0 / 207 (0.00%)	0 / 485 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (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
rectal cancer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid adenoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
circulatory collapse			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (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
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subclavian vein thrombosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
bile duct stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
cholecystectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	2 / 700 (0.29%)	0 / 25 (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
duodenal sphincterotomy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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 hiatus repair			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreaticoduodenectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
tonsillectomy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureteral stent insertion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 operation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed[2]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hellp syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 78 (0.00%)	1 / 215 (0.47%)	0 / 15 (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
pre-eclampsia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[4]	0 / 78 (0.00%)	1 / 215 (0.47%)	0 / 15 (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			
death			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
drug hypersensitivity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
cystocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[5]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[6]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
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 21.1			
subjects affected / exposed[7]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectocele			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[8]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
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			
asthma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mood swings			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizophrenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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-induced liver injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
cardiac electrophysiologic study			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
catheterisation cardiac			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endoscopic retrograde cholangiopancreatography			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
alcohol poisoning			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 contusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

muscle rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 complication			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 compression fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
congenital ectopic pancreas			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 pyelocaliectasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriospasm coronary			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 occlusion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve incompetence			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (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
palpitations			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia paroxysmal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular hypokinesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
carotid artery stenosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intracranial aneurysm			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meralgia paraesthetica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple sclerosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parkinson's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 encephalopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphadenopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
tinnitus			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
retinal detachment			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
anal fistula			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 gastrointestinal bleeding			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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

diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 ulcer			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 relapsing			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
dermatitis contact			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 eruption			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 reaction with eosinophilia and systemic symptoms			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	2 / 285 (0.70%)	1 / 700 (0.14%)	0 / 25 (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
pustular psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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 colic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
hyperparathyroidism			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid mass			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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			
bone pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exostosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 chest pain			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhabdomyolysis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 pharyngeal			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
chronic sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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
chronic tonsillitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridial sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

endometritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[9]	0 / 78 (0.00%)	0 / 215 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 empyema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 bacterial infection			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious mononucleosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injection site cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis aseptic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

necrotising fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pilonidal cyst			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 osteomyelitis alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 bacterial alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
acidosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperkalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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 21.1			

subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
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.

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

Non-serious adverse events	PBO-induction period	IXE80Q4W-induction period	IXE80Q2W-induction period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	128 / 431 (29.70%)	159 / 432 (36.81%)	170 / 433 (39.26%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	1	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 431 (0.46%)	4 / 432 (0.93%)	1 / 433 (0.23%)
occurrences (all)	2	4	1
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	15 / 431 (3.48%)	16 / 432 (3.70%)	18 / 433 (4.16%)
occurrences (all)	18	21	19
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	18 / 432 (4.17%)	28 / 433 (6.47%)
occurrences (all)	0	24	40
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 431 (1.16%)	27 / 432 (6.25%)	42 / 433 (9.70%)
occurrences (all)	5	47	77
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 431 (0.93%)	10 / 432 (2.31%)	9 / 433 (2.08%)
occurrences (all)	5	11	11
pancreatitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 431 (1.39%)	4 / 432 (0.93%)	7 / 433 (1.62%)
occurrences (all)	6	4	7
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 431 (0.46%)	2 / 432 (0.46%)	2 / 433 (0.46%)
occurrences (all)	2	2	2
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 431 (1.62%)	4 / 432 (0.93%)	3 / 433 (0.69%)
occurrences (all)	7	4	3
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	12 / 431 (2.78%)	10 / 432 (2.31%)	6 / 433 (1.39%)
occurrences (all)	12	10	6
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 431 (0.46%)	4 / 432 (0.93%)	4 / 433 (0.92%)
occurrences (all)	2	4	4
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	16 / 431 (3.71%)	2 / 432 (0.46%)	4 / 433 (0.92%)
occurrences (all)	16	2	4
urticaria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	4 / 433 (0.92%)
occurrences (all)	0	1	4
Psychiatric disorders			

insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	3 / 433 (0.69%)
occurrences (all)	0	1	3
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	9 / 431 (2.09%)	4 / 432 (0.93%)	9 / 433 (2.08%)
occurrences (all)	11	4	12
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 431 (0.93%)	6 / 432 (1.39%)	4 / 433 (0.92%)
occurrences (all)	4	6	6
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	2 / 433 (0.46%)
occurrences (all)	0	1	2
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	1 / 432 (0.23%)	0 / 433 (0.00%)
occurrences (all)	0	1	0
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	2 / 432 (0.46%)	1 / 433 (0.23%)
occurrences (all)	1	2	1
eye infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	0 / 433 (0.00%)
occurrences (all)	1	0	0
influenza			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 431 (0.00%)	4 / 432 (0.93%)	2 / 433 (0.46%)
occurrences (all)	0	4	2
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	41 / 431 (9.51%)	45 / 432 (10.42%)	49 / 433 (11.32%)
occurrences (all)	45	46	57
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 431 (1.39%)	3 / 432 (0.69%)	2 / 433 (0.46%)
occurrences (all)	6	3	2
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 431 (0.93%)	6 / 432 (1.39%)	5 / 433 (1.15%)
occurrences (all)	4	6	5
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 431 (0.23%)	0 / 432 (0.00%)	1 / 433 (0.23%)
occurrences (all)	1	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	16 / 431 (3.71%)	20 / 432 (4.63%)	24 / 433 (5.54%)
occurrences (all)	17	20	27
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	8 / 431 (1.86%)	6 / 432 (1.39%)	2 / 433 (0.46%)
occurrences (all)	8	6	2

Non-serious adverse events	IXE/PBO-maintenance primary population	IXE/IXE80Q12W-maintenance primary population	IXE/IXE80Q4W-maintenance primary population
Total subjects affected by non-serious adverse events			
subjects affected / exposed	83 / 226 (36.73%)	122 / 227 (53.74%)	115 / 229 (50.22%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences (all)	0	0	1
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences (all)	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 226 (0.88%)	5 / 227 (2.20%)	2 / 229 (0.87%)
occurrences (all)	3	6	2
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 226 (2.21%)	16 / 227 (7.05%)	8 / 229 (3.49%)
occurrences (all)	7	19	11
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	3 / 227 (1.32%)	5 / 229 (2.18%)
occurrences (all)	0	3	8
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 226 (0.88%)	7 / 227 (3.08%)	12 / 229 (5.24%)
occurrences (all)	2	10	47
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	8 / 226 (3.54%)	4 / 227 (1.76%)	8 / 229 (3.49%)
occurrences (all)	8	4	8
pancreatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	1 / 229 (0.44%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 226 (0.88%)	3 / 227 (1.32%)	3 / 229 (1.31%)
occurrences (all)	2	4	3
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 226 (0.88%)	1 / 227 (0.44%)	5 / 229 (2.18%)
occurrences (all)	2	1	5
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 226 (1.33%)	2 / 227 (0.88%)	0 / 229 (0.00%)
occurrences (all)	4	4	0
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 226 (1.33%)	4 / 227 (1.76%)	6 / 229 (2.62%)
occurrences (all)	4	4	6
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	2 / 229 (0.87%)
occurrences (all)	0	0	2
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 226 (2.21%)	6 / 227 (2.64%)	2 / 229 (0.87%)
occurrences (all)	5	6	2
urticaria			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	4 / 229 (1.75%)
occurrences (all)	0	0	4
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	0 / 229 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 226 (2.65%)	13 / 227 (5.73%)	13 / 229 (5.68%)
occurrences (all)	6	15	16
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 226 (3.10%)	13 / 227 (5.73%)	6 / 229 (2.62%)
occurrences (all)	8	15	6
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 226 (1.33%)	1 / 227 (0.44%)	3 / 229 (1.31%)
occurrences (all)	3	1	4
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 226 (0.44%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 226 (0.00%)	1 / 227 (0.44%)	2 / 229 (0.87%)
occurrences (all)	0	1	2
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 226 (0.44%)	6 / 227 (2.64%)	1 / 229 (0.44%)
occurrences (all)	1	8	1
eye infection			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 226 (0.00%)	0 / 227 (0.00%)	0 / 229 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 226 (1.77%)	8 / 227 (3.52%)	7 / 229 (3.06%)
occurrences (all)	5	8	7
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	26 / 226 (11.50%)	41 / 227 (18.06%)	51 / 229 (22.27%)
occurrences (all)	32	65	71
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 226 (2.21%)	8 / 227 (3.52%)	1 / 229 (0.44%)
occurrences (all)	5	10	1
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 226 (3.10%)	11 / 227 (4.85%)	8 / 229 (3.49%)
occurrences (all)	8	13	8
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 226 (0.44%)	1 / 227 (0.44%)	1 / 229 (0.44%)
occurrences (all)	1	1	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	18 / 226 (7.96%)	20 / 227 (8.81%)	18 / 229 (7.86%)
occurrences (all)	26	22	21
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 226 (1.33%)	2 / 227 (0.88%)	10 / 229 (4.37%)
occurrences (all)	3	2	10

Non-serious adverse events	PBOResp/PBO-maintenance secondary population	PBONonR/IXE80Q4W-maintenance secondary population	IXE80Q4WNonR/IXE80Q4W-maintenance secondary population
Total subjects affected by non-serious adverse events			

subjects affected / exposed	8 / 16 (50.00%)	211 / 391 (53.96%)	55 / 78 (70.51%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	2 / 391 (0.51%)	0 / 78 (0.00%)
occurrences (all)	1	4	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	4 / 391 (1.02%)	1 / 78 (1.28%)
occurrences (all)	1	6	1
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	20 / 391 (5.12%)	6 / 78 (7.69%)
occurrences (all)	0	26	9
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	13 / 391 (3.32%)	3 / 78 (3.85%)
occurrences (all)	0	15	6
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	36 / 391 (9.21%)	7 / 78 (8.97%)
occurrences (all)	0	94	27
Gastrointestinal disorders			

diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	22 / 391 (5.63%)	1 / 78 (1.28%)
occurrences (all)	0	29	1
pancreatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	12 / 391 (3.07%)	5 / 78 (6.41%)
occurrences (all)	0	12	6
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	2 / 391 (0.51%)	0 / 78 (0.00%)
occurrences (all)	1	2	0
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 391 (0.26%)	2 / 78 (2.56%)
occurrences (all)	0	1	3
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	9 / 391 (2.30%)	1 / 78 (1.28%)
occurrences (all)	1	9	1
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 391 (0.26%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	4 / 391 (1.02%)	2 / 78 (2.56%)
occurrences (all)	2	4	2
urticaria			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	2 / 391 (0.51%)	0 / 78 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	14 / 391 (3.58%)	8 / 78 (10.26%)
occurrences (all)	0	16	10
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	16 / 391 (4.09%)	1 / 78 (1.28%)
occurrences (all)	0	16	1
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	7 / 391 (1.79%)	4 / 78 (5.13%)
occurrences (all)	0	11	4
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 391 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	4 / 391 (1.02%)	5 / 78 (6.41%)
occurrences (all)	0	4	8
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	3 / 391 (0.77%)	4 / 78 (5.13%)
occurrences (all)	0	3	5
eye infection			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	2 / 391 (0.51%)	0 / 78 (0.00%)
occurrences (all)	1	2	0
influenza			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	7 / 391 (1.79%)	2 / 78 (2.56%)
occurrences (all)	0	7	2
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	77 / 391 (19.69%)	19 / 78 (24.36%)
occurrences (all)	0	116	25
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	13 / 391 (3.32%)	1 / 78 (1.28%)
occurrences (all)	1	15	1
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 16 (6.25%)	18 / 391 (4.60%)	3 / 78 (3.85%)
occurrences (all)	1	20	3
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 391 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 16 (12.50%)	53 / 391 (13.55%)	8 / 78 (10.26%)
occurrences (all)	4	76	12
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 16 (0.00%)	11 / 391 (2.81%)	4 / 78 (5.13%)
occurrences (all)	0	13	5

Non-serious adverse events	IXE80Q2WNonR/IXE80Q4W-maintenance secondary population	IXE80Q4W-maintenance relapse population	PBO-long term extension period

Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 62 (54.84%)	114 / 348 (32.76%)	8 / 26 (30.77%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	6 / 348 (1.72%)	0 / 26 (0.00%)
occurrences (all)	2	11	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	2 / 348 (0.57%)	0 / 26 (0.00%)
occurrences (all)	0	9	0
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	13 / 348 (3.74%)	0 / 26 (0.00%)
occurrences (all)	10	37	0

Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	8 / 348 (2.30%)	1 / 26 (3.85%)
occurrences (all)	2	9	1
pancreatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	2 / 348 (0.57%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	4 / 348 (1.15%)	0 / 26 (0.00%)
occurrences (all)	0	5	0
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	4 / 348 (1.15%)	0 / 26 (0.00%)
occurrences (all)	3	4	0
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	4 / 348 (1.15%)	0 / 26 (0.00%)
occurrences (all)	5	4	0

urticaria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	3 / 348 (0.86%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 62 (4.84%)	4 / 348 (1.15%)	1 / 26 (3.85%)
occurrences (all)	3	4	1
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 62 (9.68%)	6 / 348 (1.72%)	0 / 26 (0.00%)
occurrences (all)	6	6	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	3 / 348 (0.86%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	4 / 348 (1.15%)	0 / 26 (0.00%)
occurrences (all)	3	4	0

eye infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	0 / 348 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	3 / 348 (0.86%)	2 / 26 (7.69%)
occurrences (all)	2	4	2
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	11 / 62 (17.74%)	37 / 348 (10.63%)	4 / 26 (15.38%)
occurrences (all)	16	45	7
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 62 (1.61%)	6 / 348 (1.72%)	0 / 26 (0.00%)
occurrences (all)	1	6	0
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	11 / 348 (3.16%)	0 / 26 (0.00%)
occurrences (all)	3	11	0
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 62 (0.00%)	1 / 348 (0.29%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	4 / 62 (6.45%)	18 / 348 (5.17%)	2 / 26 (7.69%)
occurrences (all)	4	21	4
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 62 (3.23%)	11 / 348 (3.16%)	0 / 26 (0.00%)
occurrences (all)	4	13	0

Non-serious adverse events	IXE-long term extension period	Total IXE-long term extension period	PBO-follow-up period
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	414 / 1054 (39.28%)	414 / 1075 (38.51%)	3 / 18 (16.67%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 1054 (0.66%)	7 / 1075 (0.65%)	0 / 18 (0.00%)
occurrences (all)	7	7	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	10 / 1054 (0.95%)	10 / 1075 (0.93%)	0 / 18 (0.00%)
occurrences (all)	14	14	0
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	30 / 1054 (2.85%)	30 / 1075 (2.79%)	0 / 18 (0.00%)
occurrences (all)	39	39	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	0 / 18 (0.00%)
occurrences (all)	6	6	0
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	27 / 1054 (2.56%)	27 / 1075 (2.51%)	0 / 18 (0.00%)
occurrences (all)	302	302	0

Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	21 / 1054 (1.99%)	21 / 1075 (1.95%)	0 / 18 (0.00%)
occurrences (all)	24	24	0
pancreatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	30 / 1054 (2.85%)	30 / 1075 (2.79%)	0 / 18 (0.00%)
occurrences (all)	33	33	0
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	6 / 1054 (0.57%)	6 / 1075 (0.56%)	0 / 18 (0.00%)
occurrences (all)	10	10	0
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	3 / 1054 (0.28%)	3 / 1075 (0.28%)	1 / 18 (5.56%)
occurrences (all)	3	3	1
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	12 / 1054 (1.14%)	12 / 1075 (1.12%)	0 / 18 (0.00%)
occurrences (all)	13	13	0
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1054 (0.00%)	0 / 1075 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	21 / 1054 (1.99%)	21 / 1075 (1.95%)	0 / 18 (0.00%)
occurrences (all)	23	23	0

urticaria			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	7 / 1054 (0.66%)	7 / 1075 (0.65%)	0 / 18 (0.00%)
occurrences (all)	8	8	0
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	11 / 1054 (1.04%)	11 / 1075 (1.02%)	1 / 18 (5.56%)
occurrences (all)	11	11	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	54 / 1054 (5.12%)	54 / 1075 (5.02%)	0 / 18 (0.00%)
occurrences (all)	70	70	0
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	45 / 1054 (4.27%)	45 / 1075 (4.19%)	1 / 18 (5.56%)
occurrences (all)	50	50	1
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	17 / 1054 (1.61%)	17 / 1075 (1.58%)	0 / 18 (0.00%)
occurrences (all)	18	18	0
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 1054 (0.47%)	5 / 1075 (0.47%)	0 / 18 (0.00%)
occurrences (all)	5	5	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	14 / 1054 (1.33%)	14 / 1075 (1.30%)	0 / 18 (0.00%)
occurrences (all)	14	14	0
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	17 / 1054 (1.61%)	17 / 1075 (1.58%)	0 / 18 (0.00%)
occurrences (all)	22	22	0

eye infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1054 (0.09%)	1 / 1075 (0.09%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
influenza			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	28 / 1054 (2.66%)	28 / 1075 (2.60%)	0 / 18 (0.00%)
occurrences (all)	31	31	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	178 / 1054 (16.89%)	178 / 1075 (16.56%)	0 / 18 (0.00%)
occurrences (all)	314	314	0
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	33 / 1054 (3.13%)	33 / 1075 (3.07%)	0 / 18 (0.00%)
occurrences (all)	44	44	0
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	46 / 1054 (4.36%)	46 / 1075 (4.28%)	0 / 18 (0.00%)
occurrences (all)	56	56	0
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 1054 (0.47%)	5 / 1075 (0.47%)	1 / 18 (5.56%)
occurrences (all)	5	5	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	89 / 1054 (8.44%)	89 / 1075 (8.28%)	0 / 18 (0.00%)
occurrences (all)	129	129	0
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	31 / 1054 (2.94%)	31 / 1075 (2.88%)	0 / 18 (0.00%)
occurrences (all)	48	48	0

Non-serious adverse events	IXE80Q2W-follow-up period	IXE80Q4W-follow-up period	IXE80Q12W-follow-up period
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	15 / 285 (5.26%)	33 / 700 (4.71%)	2 / 25 (8.00%)
Investigations			
blood glucose increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
foreign body in eye			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

diarrhoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	2 / 700 (0.29%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
pancreatitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
nail psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	5 / 285 (1.75%)	11 / 700 (1.57%)	2 / 25 (8.00%)
occurrences (all)	5	11	2
urticaria			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	3 / 700 (0.43%)	0 / 25 (0.00%)
occurrences (all)	1	4	0
back pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
cystitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
eye infection			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 285 (0.70%)	3 / 700 (0.43%)	0 / 25 (0.00%)
occurrences (all)	2	3	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 285 (0.35%)	9 / 700 (1.29%)	0 / 25 (0.00%)
occurrences (all)	1	9	0
pharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 285 (0.70%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
staphylococcal infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	0 / 700 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	1 / 700 (0.14%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 285 (0.00%)	2 / 700 (0.29%)	0 / 25 (0.00%)
occurrences (all)	0	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 March 2017	The overall changes were to add IBD adjudication consistent with compound-level decision as IBD, specifically Crohn's disease and ulcerative colitis, has been demonstrated to occur more frequently in people with psoriasis. Thus, IBD is a reasonably anticipated event. 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