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

Summary

EudraCT number	2011-004350-26
Trial protocol	DE CZ ES NL AT PL GB
Global end of trial date	18 June 2019

Results information

Result version number	v1 (current)
This version publication date	25 June 2020
First version publication date	25 June 2020

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHBA

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01597245
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12973

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	18 June 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czech Republic: 18
Country: Number of subjects enrolled	Canada: 288
Country: Number of subjects enrolled	Austria: 23
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Romania: 35
Country: Number of subjects enrolled	United States: 369
Country: Number of subjects enrolled	Poland: 102
Country: Number of subjects enrolled	United Kingdom: 33
Country: Number of subjects enrolled	Australia: 51
Country: Number of subjects enrolled	France: 65
Country: Number of subjects enrolled	Germany: 179
Country: Number of subjects enrolled	Spain: 55
Worldwide total number of subjects	1224
EEA total number of subjects	516

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1147
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

This study has 5 periods: Period 1 - Screening; Period 2 - Blinded Induction Dosing Period (Weeks 0 to 12); Period 3 - Blinded Maintenance Dosing Period (Weeks 12 - 60); Period 4 - Long-Term Extension Period (Weeks 60 - 264); Period 5 - Post-Treatment Follow-Up Period (A Minimum of 12 Weeks)

Period 1

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

Arms

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

Arm description:

Placebo was administered as 2 subcutaneous (SC) injections at week 0, followed by 1 injection at weeks 2, 4, 6, 8, 10. Placebo for ETN (1 SC injection) administered twice weekly (every 3 to 4 days) starting at Week 0 up to Week 12.

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

Dosage and administration details:

Placebo was administered as 2 subcutaneous (SC) injections at week 0, followed by 1 injection at weeks 2, 4, 6, 8, 10. Placebo for ETN (1 SC injection) administered twice weekly (every 3 to 4 days) starting at Week 0 up to Week 12.

Arm title	50 mg Etanercept (ETN) - Induction Period

Arm description:

50 milligrams (mg) ETN was administered by 1 SC injection twice weekly (every 3-4 days) up to Week 12. Placebo for ixe was administered as 2 SC injections at Week 0 followed by Placebo for ixe administered as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).

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

Dosage and administration details:

50 milligrams (mg) ETN was administered by 1 SC injection twice weekly (every 3-4 days) up to Week 12.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for ixe was administered as 2 SC injections at Week 0 followed by Placebo for ixe administered as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).

Arm title	Ixe Q4W - Induction Period

Arm description:

160 mg ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W:Weeks 4 and 8). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

160 mg ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W:Weeks 4 and 8).

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 1 SC injection at Weeks 2, 6, and 10. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.

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. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

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.

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

Dosage and administration details:

Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.

Number of subjects in period 1	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period
Started	168	358	347
Received at least 1 dose of study drug	167	357	347
Completed	158	333	328
Not completed	10	25	19
Consent withdrawn by subject	2	8	6
Physician decision	1	-	-
Adverse event, non-fatal	1	5	5
Lost to follow-up	1	5	2
Protocol deviation	2	4	5
Lack of efficacy	3	3	1

Number of subjects in period 1	Ixe Q2W - Induction Period
Started	351
Received at least 1 dose of study drug	350
Completed	342
Not completed	9
Consent withdrawn by subject	2
Physician decision	1
Adverse event, non-fatal	4
Lost to follow-up	-
Protocol deviation	2
Lack of efficacy	-

Period 2

Period 2 title	Maintenance Period (Week 12 to Week 60)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	No
Arm title	Ixe/Placebo- Maintenance Period Primary Population (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 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 and a Placebo for ixe 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, Q4W from Weeks 12 - 56.

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

Dosage and administration details:

Placebo for ixe injection at Week 12 followed by 80 mg ixe 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 and a Placebo for ixe injection at Week 12 followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56. To maintain blinding with Q4W dose regimen, Placebo for ixe given as 1 SC injection at Weeks 16, 20, 28, 32, 40, 44, 52, and 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 and followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56.

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

Dosage and administration details:

Placebo for ixe injection at Week 12. To maintain blinding with Q4W dose regimen, Placebo for ixe given

as 1 SC injection at Weeks 16, 20, 28, 32, 40, 44, 52, and 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 NonResp/Ixe Q4W - Maintenance Period Secondary Pop

Arm description:

Participants who received placebo in Induction Period (Weeks 0 to 10) and classified as non-responders (NonResp) 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 (NonResp) 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	ETN Resp/Placebo Maintenance Period Secondary Pop

Arm description:

Participants who received ETN 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 ETN 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	ETN NonResp/Ixe Q4W - Maintenance Period Secondary Pop

Arm description:

Participants who received ETN in Induction Period (Weeks 0 to 12) and classified as non-responders were administered 2 SC injections of placebo 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:

80 mg ixe as 1 SC injection Q4W from Weeks 16 - 60.

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:

2 SC injections of placebo were administered at Week 12.

Arm title	Ixe Q4W NonResp/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 and a Placebo for ixe 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.

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

Dosage and administration details:

Placebo for ixe injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Arm title	Ixe Q2W NonResp/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 and a Placebo for ixe 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.

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

Dosage and administration details:

Placebo for ixe injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Number of subjects in period 2	Ixe/Placebo-Maintenance Period Primary Population (Pop)	Ixe/Ixe Q4W - Maintenance Period Primary Pop	Ixe/Ixe Q12W - Maintenance Period Primary Pop
Started	176	187	181
Participants received one dose	176	187	181
Completed	15	149	92
Not completed	161	38	89
Consent withdrawn by subject	3	3	1
Physician decision	-	1	-
Relapsed	150	22	80
Adverse event, non-fatal	4	6	6
On study treatment	-	1	1
Sponsor Decision	-	-	-
Lost to follow-up	3	4	1
Protocol deviation	1	-	-
Lack of efficacy	-	1	-

Number of subjects in period 2	Placebo Resp/Placebo - Maintenance Period Secondary Pop	Placebo NonResp/Ixe Q4W - Maintenance Period Secondary Pop	ETN Resp/Placebo Maintenance Period Secondary Pop
Started	3	155	132
Participants received one dose	3	155	132
Completed	0	135	11
Not completed	3	20	121
Consent withdrawn by subject	-	4	1
Physician decision	-	1	1
Relapsed	2	-	114
Adverse event, non-fatal	1	8	2
On study treatment	-	-	-
Sponsor Decision	-	-	-
Lost to follow-up	-	1	2
Protocol deviation	-	3	1

Lack of efficacy	-	3	-

Number of subjects in period 2	ETN NonResp/Ixe Q4W - Maintenance Period Secondary Pop	Ixe Q4W NonResp/Ixe Q4W- Maintenance Period Secondary Pop	Ixe Q2W NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Started	200	75	49
Participants received one dose	200	75	49
Completed	178	56	37
Not completed	22	19	12
Consent withdrawn by subject	6	5	4
Physician decision	1	1	-
Relapsed	-	-	-
Adverse event, non-fatal	8	1	2
On study treatment	-	-	-
Sponsor Decision	1	-	-
Lost to follow-up	2	2	1
Protocol deviation	2	-	1
Lack of efficacy	2	10	4

Period 3

Period 3 title	Long Term Extension (Week 60 - Week 264)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Placebo Long-Term Extension (LTE)

Arm description:

Participants who received placebo at the start of long-term extension period (Week 60) and could be switched to ixe. Data while participants were on placebo were included.

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 at the start of long-term extension period (Week 60) and could be switched to ixe. Data while participants were on placebo were included.

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 long-term extension (LTE) period.

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

Dosage and administration details:

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 long-term extension (LTE) period.

Number of subjects in period 3	Placebo Long-Term Extension (LTE)	Ixe Long-Term Extension	Total Ixe Long-term Extension
Started	26	979	1002
Completed	0	754	774
Not completed	26	225	228
Adverse event, serious fatal	-	8	8
Consent withdrawn by subject	1	62	63
Physician decision	1	11	12
Clinical Relapse	-	4	4
Adverse event, non-fatal	1	69	70
Switched from PBO to Ixe	23	-	-
Sponsor Decision	-	1	1
Lost to follow-up	-	38	38
Lack of efficacy	-	26	26
Protocol deviation	-	6	6

Period 4

Period 4 title	Post-Treatment Follow-Up (12 - 24 Weeks)
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 immediately 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 infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Arm title	ETN Post-Treatment Follow-Up

Arm description:

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

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

Dosage and administration details:

Participants who received ETN immediately 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 immediately 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 immediately 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 1 SC injection Q4W immediately 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 Q4W immediately 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 1 SC injection Q2W immediately 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 Q2W immediately 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	Placebo Post-Treatment Follow-Up	ETN Post-Treatment Follow-Up	Ixe Q12W Post-Treatment Follow-Up
Started	16	6	24
Completed	0	0	14
Not completed	16	6	10
Physician decision	1	-	-
Consent withdrawn by subject	-	1	1
Clinical Relapse	-	-	-
Adverse event, non-fatal	9	5	8
Sponsor Decision	1	-	-
Lost to follow-up	-	-	1
Entry Criteria Not Met	2	-	-
Lack of efficacy	2	-	-
Protocol deviation	1	-	-

Number of subjects in period 4	Ixe Q4W Post-Treatment Follow-Up	Ixe Q2W Post-Treatment Follow-Up
Started	656	248
Completed	489	212
Not completed	167	36
Physician decision	9	1
Consent withdrawn by subject	41	13
Clinical Relapse	1	-
Adverse event, non-fatal	63	13

Sponsor Decision	1	-
Lost to follow-up	14	4
Entry Criteria Not Met	3	-
Lack of efficacy	29	3
Protocol deviation	6	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo - Induction Period
Reporting group description:	
Placebo was administered as 2 subcutaneous (SC) injections at week 0, followed by 1 injection at weeks 2, 4, 6, 8, 10. Placebo for ETN (1 SC injection) administered twice weekly (every 3 to 4 days) starting at Week 0 up to Week 12.	
Reporting group title	50 mg Etanercept (ETN) - Induction Period
Reporting group description:	
50 milligrams (mg) ETN was administered by 1 SC injection twice weekly (every 3-4 days) up to Week 12. Placebo for ixe was administered as 2 SC injections at Week 0 followed by Placebo for ixe administered as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).	
Reporting group title	Ixe Q4W - Induction Period
Reporting group description:	
160 mg ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W:Weeks 4 and 8). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.	
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. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.	

Reporting group values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period
Number of subjects	168	358	347
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	159	337	324
From 65-84 years	9	21	23
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	48	122	103
Male	120	236	244
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	11	26	24
Not Hispanic or Latino	130	279	271
Unknown or Not Reported	27	53	52
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	0	2

Asian	6	8	11
Native Hawaiian or Other Pacific Islander	1	1	1
Black or African American	10	13	11
White	149	331	315
More than one race	0	1	3
Unknown or Not Reported	0	4	4
Region of Enrollment Units: Subjects			
Canada	40	82	82
Austria	2	10	6
Netherlands	1	2	2
Czechia	3	6	3
Romania	6	9	8
United States	49	111	105
Poland	14	30	28
United Kingdom	4	9	9
Australia	7	13	15
France	7	18	21
Germany	28	53	51
Spain	7	15	17
Baseline in Static Physician Global Assessment (sPGA)			
The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. The sPGA is recommended as an endpoint to use to assess efficacy in the treatment of Ps (EMEA 2004). Overall lesions are categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's Ps is assessed at a given time point on a 6-point scale in which 0 = cleared, 1 = minimal, 2 = mild, 3 = moderate; 4 = severe, 5 = very severe.			
Units: Subjects			
sPGA = 3	86	186	166
sPGA = 4, 5	82	172	181
Baseline in Participants Achieving Psoriasis Area and Severity Index (PASI) Score			
PASI is another accepted primary efficacy measurement for this phase of development of Ps treatments. The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation, erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 or no Ps to 72 for the most severe disease.			
Units: units on a scale			
arithmetic mean	20.57	19.07	20.04
standard deviation	± 8.366	± 6.701	± 6.962
Baseline Dermatology-Specific Quality of Life Index (DLQI) Total Score			
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 impairment.			
Units: units on a scale			
arithmetic mean	12.8	12.7	11.6
standard deviation	± 7.24	± 7.03	± 6.65
Baseline in Nail Psoriasis Severity Index (NAPSI) Total Score			
The NAPSI scale evaluates Ps severity in the fingernail bed and fingernail matrix with each divided into quadrants. Scores range from 0 (none) to 4 (Ps in all 4 quadrants), depending on the presence (score of 1) or absence (score of 0) of Ps in each quadrant of the fingernail bed or matrix. NAPSI score of a fingernail is the sum of scores from each quadrant of the fingernail bed and fingernail matrix (maximum			

of 8). The total NAPSI score equals the sum of all fingernails and ranges from 0 to 80. Higher scores indicate more severe Ps.			
Units: units on a scale			
arithmetic mean	27.62	30.44	23.70
standard deviation	± 20.937	± 20.648	± 18.696
Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score			
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 score ranging from 0 (less severity) to 72 (more severity).			
Units: units on a scale			
arithmetic mean	21.0	20.0	20.8
standard deviation	± 15.24	± 15.19	± 15.63
Baseline in Body Surface Area (BSA) Total Score			
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 participant's hand (includes the palm, fingers and thumb). Total BSA is the sum of handprints from the affected areas.			
Units: units on a scale			
arithmetic mean	27.2	25.3	27.0
standard deviation	± 18.12	± 15.50	± 17.23
Baseline in Quick Inventory of Depressive Symptomatology Self Report 16 items (QIDS-SR16) Score			
QIDS-SR16 is a participant-administered, 16-item instrument assesses the existence and severity of symptoms of depression. A participant is asked a statement relating to the way they have felt for the past 7 days and rate on a 4-point scale: 0 (best) to 3 (worst). The sum of the domains [sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance, 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.			
Units: units on a scale			
arithmetic mean	4.7	4.5	4.4
standard deviation	± 4.14	± 4.07	± 4.04
Baseline in Patient's Global Assessment (PatGA) Total Score			
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).			
Units: units on a scale			
arithmetic mean	4.0	4.0	4.1
standard deviation	± 0.92	± 0.96	± 0.90
Baseline in Work Productivity Activity Impairment - Psoriasis			
Absenteeism Score			
Units: units on a scale			
arithmetic mean	4.3	3.7	4.6
standard deviation	± 16.61	± 15.24	± 17.65
Baseline in Work Productivity Activity Impairment Questionnaire - Psoriasis			
Active Impairment Score			
Units: units on a scale			
arithmetic mean	30.2	31.3	29.4
standard deviation	± 28.87	± 29.04	± 29.28
Baseline in Work Productivity Impairment Questionnaire - Psoriasis			
Presenteeism Score			

Units: units on a scale			
arithmetic mean	24.3	21.2	22.3
standard deviation	± 26.19	± 25.42	± 24.77
Baseline in Work Productivity Activity Impairment Questionnaire-Psoriasis			
Work Productivity Loss			
Units: units on a scale			
arithmetic mean	26.1	22.3	24.6
standard deviation	± 28.11	± 26.52	± 27.41
Baseline in Short form (36 Items) Health Survey SF-36 Total Score			
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 Physical Component Score (PCS) and Mental Component Score (MCS) scores. Scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. Physical Summary Score			
Units: units on a scale			
arithmetic mean	47.7094	47.5268	47.6231
standard deviation	± 9.5043	± 9.0729	± 8.9693
Baseline in SF-36 Total Score			
Mental Summary Score			
Units: units on a scale			
arithmetic mean	47.7889	48.7097	49.0131
standard deviation	± 10.6183	± 10.6546	± 10.9087

Reporting group values	Ixe Q2W - Induction Period	Total	
Number of subjects	351	1224	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	327	1147	
From 65-84 years	24	77	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	130	403	
Male	221	821	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	19	80	
Not Hispanic or Latino	274	954	
Unknown or Not Reported	58	190	
Race (NIH/OMB) Units: Subjects			

American Indian or Alaska Native	2	6	
Asian	12	37	
Native Hawaiian or Other Pacific Islander	0	3	
Black or African American	5	39	
White	330	1125	
More than one race	1	5	
Unknown or Not Reported	1	9	
Region of Enrollment Units: Subjects			
Canada	84	288	
Austria	5	23	
Netherlands	1	6	
Czechia	6	18	
Romania	12	35	
United States	104	369	
Poland	30	102	
United Kingdom	11	33	
Australia	16	51	
France	19	65	
Germany	47	179	
Spain	16	55	
Baseline in Static Physician Global Assessment (sPGA)			
The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. The sPGA is recommended as an endpoint to use to assess efficacy in the treatment of Ps (EMEA 2004). Overall lesions are categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's Ps is assessed at a given time point on a 6-point scale in which 0 = cleared, 1 = minimal, 2 = mild, 3 = moderate; 4 = severe, 5 = very severe.			
Units: Subjects			
sPGA = 3	178	616	
sPGA = 4, 5	173	608	
Baseline in Participants Achieving Psoriasis Area and Severity Index (PASI) Score			
PASI is another accepted primary efficacy measurement for this phase of development of Ps treatments. The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation, erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 or no Ps to 72 for the most severe disease.			
Units: units on a scale			
arithmetic mean	19.35		
standard deviation	± 7.339	-	
Baseline Dermatology-Specific Quality of Life Index (DLQI) Total Score			
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 impairment.			
Units: units on a scale			
arithmetic mean	12.4		
standard deviation	± 6.86	-	
Baseline in Nail Psoriasis Severity Index (NAPSI) Total Score			
The NAPSI scale evaluates Ps severity in the fingernail bed and fingernail matrix with each divided into quadrants. Scores range from 0 (none) to 4 (Ps in all 4 quadrants), depending on the presence (score of			

1) or absence (score of 0) of Ps in each quadrant of the fingernail bed or matrix. NAPSI score of a fingernail is the sum of scores from each quadrant of the fingernail bed and fingernail matrix (maximum of 8). The total NAPSI score equals the sum of all fingernails and ranges from 0 to 80. Higher scores indicate more severe Ps.			
Units: units on a scale arithmetic mean standard deviation	 26.27 ± 20.388	 -	
Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score			
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 score ranging from 0 (less severity) to 72 (more severity).			
Units: units on a scale arithmetic mean standard deviation	 19.5 ± 14.85	 -	
Baseline in Body Surface Area (BSA) Total Score			
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 participant's hand (includes the palm, fingers and thumb). Total BSA is the sum of handprints from the affected areas.			
Units: units on a scale arithmetic mean standard deviation	 25.1 ± 15.82	 -	
Baseline in Quick Inventory of Depressive Symptomatology Self Report 16 items (QIDS-SR16) Score			
QIDS-SR16 is a participant-administered, 16-item instrument assesses the existence and severity of symptoms of depression. A participant is asked a statement relating to the way they have felt for the past 7 days and rate on a 4-point scale: 0 (best) to 3 (worst). The sum of the domains [sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance, 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.			
Units: units on a scale arithmetic mean standard deviation	 4.6 ± 3.84	 -	
Baseline in Patient's Global Assessment (PatGA) Total Score			
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).			
Units: units on a scale arithmetic mean standard deviation	 4.1 ± 0.91	 -	
Baseline in Work Productivity Activity Impairment - Psoriasis			
Absenteeism Score			
Units: units on a scale arithmetic mean standard deviation	 7.3 ± 22.15	 -	
Baseline in Work Productivity Activity Impairment Questionnaire - Psoriasis			
Active Impairment Score			
Units: units on a scale arithmetic mean standard deviation	 31.7 ± 29.64	 -	
Baseline in Work Productivity			

Impairment Questionnaire - Psoriasis			
Presenteeism Score			
Units: units on a scale arithmetic mean standard deviation	 24.2 ± 25.80	 -	
Baseline in Work Productivity Activity Impairment Questionnaire-Psoriasis			
Work Productivity Loss			
Units: units on a scale arithmetic mean standard deviation	 27.7 ± 29.19	 -	
Baseline in Short form (36 Items) Health Survey SF-36 Total Score			
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 Physical Component Score (PCS) and Mental Component Score (MCS) scores. Scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. Physical Summary Score			
Units: units on a scale arithmetic mean standard deviation	 47.6996 ± 9.03332	 -	
Baseline in SF-36 Total Score			
Mental Summary Score			
Units: units on a scale arithmetic mean standard deviation	 47.7140 ± 11.6686	 -	

Subject analysis sets

Subject analysis set title	Total Participants
Subject analysis set type	Full analysis

Subject analysis set description:

All participants with evaluable data.

Reporting group values	Total Participants		
Number of subjects	1224		
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			

Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Region of Enrollment Units: Subjects			
Canada Austria Netherlands Czechia Romania United States Poland United Kingdom Australia France Germany Spain			
Baseline in Static Physician Global Assessment (sPGA)			
The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. The sPGA is recommended as an endpoint to use to assess efficacy in the treatment of Ps (EMEA 2004). Overall lesions are categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's Ps is assessed at a given time point on a 6-point scale in which 0 = cleared, 1 = minimal, 2 = mild, 3 = moderate; 4 = severe, 5 = very severe.			
Units: Subjects			
sPGA = 3 sPGA = 4, 5			
Baseline in Participants Achieving Psoriasis Area and Severity Index (PASI) Score			
PASI is another accepted primary efficacy measurement for this phase of development of Ps treatments. The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation, erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 or no Ps to 72 for the most severe disease.			
Units: units on a scale arithmetic mean standard deviation	 19.63 ± 7.216		
Baseline Dermatology-Specific Quality of			

Life Index (DLQI) Total Score			
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 impairment.			
Units: units on a scale arithmetic mean standard deviation	 12.3 ± 6.91		
Baseline in Nail Psoriasis Severity Index (NAPSI) Total Score			
The NAPSI scale evaluates Ps severity in the fingernail bed and fingernail matrix with each divided into quadrants. Scores range from 0 (none) to 4 (Ps in all 4 quadrants), depending on the presence (score of 1) or absence (score of 0) of Ps in each quadrant of the fingernail bed or matrix. NAPSI score of a fingernail is the sum of scores from each quadrant of the fingernail bed and fingernail matrix (maximum of 8). The total NAPSI score equals the sum of all fingernails and ranges from 0 to 80. Higher scores indicate more severe Ps.			
Units: units on a scale arithmetic mean standard deviation	 26.97 ± 20.211		
Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score			
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 score ranging from 0 (less severity) to 72 (more severity).			
Units: units on a scale arithmetic mean standard deviation	 20.2 ± 15.22		
Baseline in Body Surface Area (BSA) Total Score			
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 participant's hand (includes the palm, fingers and thumb). Total BSA is the sum of handprints from the affected areas.			
Units: units on a scale arithmetic mean standard deviation	 26.0 ± 16.47		
Baseline in Quick Inventory of Depressive Symptomatology Self Report 16 items (QIDS-SR16) Score			
QIDS-SR16 is a participant-administered, 16-item instrument assesses the existence and severity of symptoms of depression. A participant is asked a statement relating to the way they have felt for the past 7 days and rate on a 4-point scale: 0 (best) to 3 (worst). The sum of the domains [sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance, 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.			
Units: units on a scale arithmetic mean standard deviation	 4.5 ± 4.00		
Baseline in Patient's Global Assessment (PatGA) Total Score			
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).			
Units: units on a scale arithmetic mean standard deviation	 4.0 ± 0.92		
Baseline in Work Productivity Activity			

Impairment - Psoriasis			
Absenteeism Score			
Units: units on a scale			
arithmetic mean	5.1		
standard deviation	± 18.40		
Baseline in Work Productivity Activity Impairment Questionnaire - Psoriasis			
Active Impairment Score			
Units: units on a scale			
arithmetic mean	30.7		
standard deviation	± 29.24		
Baseline in Work Productivity Impairment Questionnaire - Psoriasis			
Presenteeism Score			
Units: units on a scale			
arithmetic mean	22.8		
standard deviation	± 25.44		
Baseline in Work Productivity Activity Impairment Questionnaire-Psoriasis			
Work Productivity Loss			
Units: units on a scale			
arithmetic mean	25.0		
standard deviation	± 27.82		
Baseline in Short form (36 Items) Health Survey SF-36 Total Score			
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 Physical Component Score (PCS) and Mental Component Score (MCS) scores. Scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. Physical Summary Score			
Units: units on a scale			
arithmetic mean	47.6289		
standard deviation	± 9.0814		
Baseline in SF-36 Total Score			
Mental Summary Score			
Units: units on a scale			
arithmetic mean	48.3832		
standard deviation	± 11.0234		

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, followed by 1 injection at weeks 2, 4, 6, 8, 10. Placebo for ETN (1 SC injection) administered twice weekly (every 3 to 4 days) starting at Week 0 up to Week 12.	
Reporting group title	50 mg Etanercept (ETN) - Induction Period
Reporting group description:	
50 milligrams (mg) ETN was administered by 1 SC injection twice weekly (every 3-4 days) up to Week 12. Placebo for ixe was administered as 2 SC injections at Week 0 followed by Placebo for ixe administered as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).	
Reporting group title	Ixe Q4W - Induction Period
Reporting group description:	
160 mg ixe was administered as 2 SC injections at Week 0 followed by 80 mg ixe as 1 SC injection every 4 weeks (Q4W:Weeks 4 and 8). Placebo was administered as 1 SC injection at Weeks 2, 6, and 10. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.	
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. Placebo for ETN (1 SC injection) was administered twice weekly starting at Week 0 up to Week 12.	
Reporting group title	Ixe/Placebo- Maintenance Period Primary Population (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 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 and a Placebo for ixe injection at Week 12 followed by 80 mg ixe 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 and a Placebo for ixe injection at Week 12 followed by 80 mg ixe as 1 SC injection every 12 weeks (Q12W) up to and including Week 56. To maintain blinding with Q4W dose regimen, Placebo for ixe given as 1 SC injection at Weeks 16, 20, 28, 32, 40, 44, 52, and 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 NonResp/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 (NonResp) 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	ETN Resp/Placebo Maintenance Period Secondary Pop
Reporting group description:	
Participants who received ETN 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	ETN NonResp/Ixe Q4W - Maintenance Period Secondary Pop

Reporting group description:

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

Reporting group title	Ixe Q4W NonResp/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 and a Placebo for ixe 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 NonResp/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 and a Placebo for ixe injection at Week 12 followed by 80 mg ixe as 1 SC injection Q4W up to and including Week 56.

Reporting group title	Placebo Long-Term Extension (LTE)

Reporting group description:

Participants who received placebo at the start of long-term extension period (Week 60) and could be switched to ixe. Data while participants were on placebo were included.

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 long-term extension (LTE) period.

Reporting group title	Placebo Post-Treatment Follow-Up

Reporting group description:

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

Reporting group title	ETN Post-Treatment Follow-Up

Reporting group description:

Participants who received ETN immediately 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 immediately 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 1 SC injection Q4W immediately 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 1 SC injection Q2W immediately prior to entering the Post-Treatment Follow-Up period (a 12-24 week period after their last scheduled treatment visit).

Subject analysis set title	Total Participants
Subject analysis set type	Full analysis

Subject analysis set description:

All participants with evaluable data.

Primary: Percentage of Participants with a Static Physician Global Assessment (sPGA) of (0,1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: Static Physician Global Assessment [sPGA])

End point title	Percentage of Participants with a Static Physician Global Assessment (sPGA) of (0,1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: Static Physician Global Assessment [sPGA])

End point description:

The sPGA is the physician's determination of the participant's Psoriasis (Ps) lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's Ps was 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. Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for Non-Responder Imputation (NRI) analysis.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168[1]	358[2]	347[3]	351[4]
Units: percentage of participants				
number (not applicable)	2.4	36.0	72.9	83.2

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

[3] - All randomized participants.

[4] - All randomized participants.

Statistical analyses

Statistical analysis title	sPGA Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	526
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period

Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Primary: Percentage of Participants achieving Psoriasis Area and Severity Index (PASI) ≥75% (PASI75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: Psoriasis Area and Severity Index [PASI])

End point title	Percentage of Participants achieving Psoriasis Area and Severity Index (PASI) ≥75% (PASI75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: Psoriasis Area and Severity Index [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. Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168[5]	358[6]	347[7]	351[8]
Units: percentage of participants				
number (not applicable)	2.4	41.6	77.5	89.7

Notes:

[5] - All randomized participants.

[6] - All randomized participants.

[7] - All randomized participants.

[8] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI75 Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) - Induction Period v Placebo - Induction Period
Number of subjects included in analysis	526
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI75 Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI75 Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Participants Achieving an sPGA (0) (Efficacy of Ixekizumab in Participants With Moderate to Severe Chronic Plaque Psoriasis. Measure: [sPGA])

End point title	Percentage of Participants Achieving an sPGA (0) (Efficacy of Ixekizumab in Participants With Moderate to Severe Chronic Plaque Psoriasis. Measure: [sPGA])

End point description:

The sPGA is 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. Participant’s Ps was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Secondary

End point timeframe:
Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168[9]	358[10]	347[11]	351[12]
Units: percentage of participants				
number (not applicable)	0.6	5.9	32.3	41.9

Notes:
[9] - All randomized participants.
[10] - All randomized participants.
[11] - All randomized participants.
[12] - All randomized participants.

Statistical analyses

Statistical analysis title	sPGA (0) Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	526
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA (0) Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	sPGA (0) Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period

Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Participants Achieving PASI 90% (PASI90) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: [PASI])

End point title	Percentage of Participants Achieving PASI 90% (PASI90) (Efficacy of ixekizumab in participants with moderate to severe chronic 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 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 were defined as having an improvement of ≥90% in the PASI score compared to baseline. Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168[13]	358[14]	347[15]	351[16]
Units: percentage of participants				
number (not applicable)	0.6	18.7	59.7	70.7

Notes:

[13] - All randomized participants.

[14] - All randomized participants.

[15] - All randomized participants.

[16] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI90 Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period

Number of subjects included in analysis	526
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI90 Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI90 Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Participants Achieving PASI 100% (PASI100)

End point title	Percentage of Participants Achieving PASI 100% (PASI100)

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 PASI100 were defined as having an improvement of 100% in the PASI score compared to baseline. Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168[17]	358[18]	347[19]	351[20]
Units: percentage of participants				
number (not applicable)	0.6	5.3	30.8	40.5

Notes:

[17] - All randomized participants.

[18] - All randomized participants.

[19] - All randomized participants.

[20] - All randomized participants.

Statistical analyses

Statistical analysis title	PASI100 Statistical Analysis 1
Comparison groups	50 mg Etanercept (ETN) - Induction Period v Placebo - Induction Period
Number of subjects included in analysis	526
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI100 Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PASI100 Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Participants Maintaining an sPGA (0,1) from Week 12 after Re-randomization at start of Maintenance Dosing Period to Week 60

End point title	Percentage of Participants Maintaining an sPGA (0,1) from Week 12 after Re-randomization at start of Maintenance Dosing

	Period to Week 60

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. Participant's Ps was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Secondary

End point timeframe:

Week 60

End point values	Ixe/Placebo- Maintenance Period Primary Population (Pop)	Ixe/Ixe Q4W - Maintenance Period Primary Pop	Ixe/Ixe Q12W - Maintenance Period Primary Pop	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176[21]	187[22]	181[23]	
Units: Percentage of participants				
number (not applicable)	6.3	74.9	40.9	

Notes:

[21] - All randomized participants who had sPGA score of (0,1), re-randomized, and received drug.

[22] - All randomized participants who had sPGA score of (0,1), re-randomized, and received drug.

[23] - All randomized participants who had sPGA score of (0,1), re-randomized, and received drug.

Statistical analyses

Statistical analysis title	sPGA (0,1) Statistical Analysis 1
Comparison groups	Ixe/Ixe Q12W - Maintenance Period Primary Pop v Ixe/Placebo- Maintenance Period Primary Population (Pop)
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact

Statistical analysis title	sPGA (0,1) Statistical Analysis 2
Comparison groups	Ixe/Placebo- Maintenance Period Primary Population (Pop) v Ixe/Ixe Q4W - Maintenance Period Primary Pop
Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact

Secondary: Percentage of Participants with Itching Severity (Itch Numeric Rating Scale [NRI]) Score ≥4 Point Reduction from Baseline

End point title	Percentage of Participants with Itching Severity (Itch Numeric Rating Scale [NRI]) Score ≥4 Point Reduction from Baseline

End point description:

The Itch Numeric Rating Scale (NRS) is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable". The number and percentage of participants achieving an Itch NRS ≥4 point reduction from baseline were presented by treatment group for participants who had a baseline Itch NRS ≥4. Describes worst level of itching in past 24 hours. Participants who did not meet the clinical response criteria or had missing data at Week 12 were considered non-responders for NRI analysis.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	135[24]	306[25]	293[26]	303[27]
Units: percentage of participants				
number (not applicable)	14.1	57.8	76.8	85.1

Notes:

[24] - All randomized participants who had Itch NRS ≥4 at baseline.

[25] - All randomized participants who had Itch NRS ≥4 at baseline.

[26] - All randomized participants who had Itch NRS ≥4 at baseline.

[27] - All randomized participants who had Itch NRS ≥4 at baseline.

Statistical analyses

Statistical analysis title	Itch NRI Score Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	441
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Itch NRI Score Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	428
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Itch NRI Score Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	438
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Change from baseline in Dermatology-Specific Quality of Life Index (DLQI) Total Score (Quality of Life and Outcome Assessments. Measures: Participant Reported Outcomes [PRO])

End point title	Change from baseline in Dermatology-Specific Quality of Life Index (DLQI) Total Score (Quality of Life and Outcome Assessments. Measures: Participant Reported Outcomes [PRO])

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 "not relevant" and unanswered responses were scored as "0." Total scores range from 0 to 30, with higher score indicating greater quality of life 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) with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	160[28]	346[29]	338[30]	343[31]
Units: units on a scale				
least squares mean (standard error)	-2.0 (± 0.36)	-7.7 (± 0.25)	-9.4 (± 0.25)	-10.4 (± 0.25)

Notes:

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

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

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

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

Statistical analyses

Statistical analysis title	DLQI Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period

Number of subjects included in analysis	506
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	DLQI Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	DLQI Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

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

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

End point description:

The NAPSI scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix Ps. The fingernail bed and fingernail matrix are each divided into quadrants. Each fingernail is given a score for fingernail bed Ps and fingernail matrix Ps, each with scores of 0 (none) to 4 (Ps in all 4 quadrants), depending on the presence (score of 1) or absence (score of 0) of Ps in each quadrant of the fingernail bed or matrix. The NAPSI score of a fingernail is the sum of scores from each quadrant of the fingernail bed and fingernail matrix (maximum of 8). The total NAPSI score equals the sum of all fingernails and ranges from 0 to 80 with higher scores indicating more severe Ps. LS mean change from baseline in NAPSI score was calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111[32]	219[33]	215[34]	206[35]
Units: units on a scale				
least squares mean (standard error)	-0.82 (± 1.162)	-5.34 (± 0.835)	-7.39 (± 0.843)	-8.60 (± 0.853)

Notes:

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

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

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

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

Statistical analyses

Statistical analysis title	NAPSI Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis

Statistical analysis title	NAPSI Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	326
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	NAPSI Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	317
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from Baseline Psoriasis Scalp Severity Index (PSSI) Score

End point title	Change from Baseline Psoriasis Scalp Severity Index (PSSI) Score

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 (less severity) to 72 (more severity), with lower scores indicating less severity. LS mean change from baseline in PSSI score was calculated using MMRM with baseline score as a covariate, treatment, pooled center, visit, and treatment-by-visit interaction as fixed effects. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	150[36]	316[37]	307[38]	318[39]
Units: units on a scale				
least squares mean (standard error)	-3.8 (± 0.73)	-14.8 (± 0.50)	-18.5 (± 0.51)	-18.7 (± 0.50)

Notes:

[36] - All randomized participants with scalp Ps involvement at baseline and had at least 1 post-baseline.
[37] - All randomized participants with scalp Ps involvement at baseline and had at least 1 post-baseline.
[38] - All randomized participants with scalp Ps involvement at baseline and had at least 1 post-baseline.
[39] - All randomized participants with scalp Ps involvement at baseline and had at least 1 post-baseline.

Statistical analyses

Statistical analysis title	PSSI Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PSSI Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	457
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PSSI Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from Baseline in Percent of Body Surface Area (BSA) involvement of psoriasis

End point title	Change from Baseline in Percent of Body Surface Area (BSA) involvement of psoriasis

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	166[40]	350[41]	342[42]	348[43]
Units: units on a scale				
least squares mean (standard error)	0.5 (± 1.05)	-12.4 (± 0.72)	-20.3 (± 0.72)	-20.6 (± 0.71)

Notes:

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

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

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

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

Statistical analyses

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

Number of subjects included in analysis	516
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	BSA Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	508
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	BSA Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change from baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 items (QIDS-SR16) Total Score

End point title	Change from baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 items (QIDS-SR16) Total Score

End point description:

The QIDS-SR16 is a self-administered, 16-item instrument in which a participant is asked to consider each statement as it relates to the way they have felt for the past 7 days. There is a 4-point scale for each item ranging from 0 (best) to 3 (worst). The 16 items are scored to give 9 individual depression domains (sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance [initial, middle and late insomnia or hypersomnia], decrease/increase in appetite/weight, and psychomotor agitation/retardation), which are summed to give a single score ranging from 0 to 27, with higher scores denoting greater symptom severity. LS mean change from baseline in total QIDS-SR16 score was calculated using the analysis of covariance (ANCOVA) model with treatment, pooled center and baseline QIDS total score. Missing data was imputed by last observation carried forward (LOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	162[44]	342[45]	334[46]	347[47]
Units: units on a scale				
least squares mean (standard error)	0.1 (± 0.21)	-0.3 (± 0.15)	-0.7 (± 0.15)	-0.9 (± 0.15)

Notes:

[44] - All randomized participants who had baseline and at least 1 post baseline QIDS-SR16 measurement

[45] - All randomized participants who had baseline and at least 1 post baseline QIDS-SR16 measurement

[46] - All randomized participants who had baseline and at least 1 post baseline QIDS-SR16 measurement

[47] - All randomized participants who had baseline and at least 1 post baseline QIDS-SR16 measurement

Statistical analyses

Statistical analysis title	QIDS-SR16 Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	504
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.15
Method	ANCOVA

Statistical analysis title	QIDS-SR16 Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	496
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANCOVA

Statistical analysis title	QIDS-SR16 Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	509
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	87[48]	199[49]	204[50]	213[51]
Units: units on a scale				
least squares mean (standard error)				
Absenteeism	-1.5 (± 0.83)	-3.7 (± 0.55)	-3.2 (± 0.54)	-3.9 (± 0.54)

Notes:

[48] - All randomized participants who had baseline and at least 1 post baseline WPAI-PSO Absenteeism.
[49] - All randomized participants who had baseline and at least 1 post baseline WPAI-PSO Absenteeism.
[50] - All randomized participants who had baseline and at least 1 post baseline WPAI-PSO Absenteeism.
[51] - All randomized participants who had baseline and at least 1 post baseline WPAI-PSO Absenteeism.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 1

Statistical analysis description:

Absenteeism Score

Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	286
Analysis specification	Pre-specified
Analysis type	superiority[52]
P-value	= 0.026
Method	ANCOVA

Notes:

[52] - Absenteeism Score

Statistical analysis title	WPAI-PSO Statistical Analysis 2

Statistical analysis description:

Absenteeism Score

Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	291
Analysis specification	Pre-specified
Analysis type	superiority[53]
P-value	= 0.076
Method	ANCOVA

Notes:

[53] - Absenteeism Score

Statistical analysis title	WPAI-PSO Statistical Analysis 3

Statistical analysis description:

Absenteeism Score

Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	superiority[54]
P-value	= 0.016
Method	ANCOVA

Notes:

[54] - Absenteeism Score

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	160[55]	342[56]	332[57]	340[58]
Units: units on a scale				
least squares mean (standard deviation)				
Activity Impairment Score	-0.4 (± 1.46)	-16.6 (± 1.00)	-22.6 (± 1.02)	-25.8 (± 1.01)

Notes:

[55] - All randomized participants who had baseline and at least 1 post baseline activity impairment score.

[56] - All randomized participants who had baseline and at least 1 post baseline activity impairment score.
[57] - All randomized participants who had baseline and at least 1 post baseline activity impairment score.
[58] - All randomized participants who had baseline and at least 1 post baseline activity impairment score.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 4
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	502
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 5
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	492
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 6
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Secondary: Change From Baseline in Presenteeism Score of WPAI-PSO
End point title: Change From Baseline in Presenteeism Score of WPAI-PSO
End point description:
End point type: Secondary
End point timeframe: Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94[59]	217[60]	226[61]	232[62]
Units: units on a scale				
least squares mean (standard deviation)				
Presenteeism Score	-2.4 (± 1.59)	-12.4 (± 1.05)	-18.5 (± 1.03)	-18.2 (± 1.03)

Notes:

[59] - All randomized participants who had baseline and at least 1 post baseline presenteeism measurement.
[60] - All randomized participants who had baseline and at least 1 post baseline presenteeism measurement.
[61] - All randomized participants who had baseline and at least 1 post baseline presenteeism measurement.
[62] - All randomized participants who had baseline and at least 1 post baseline presenteeism measurement

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 7
Comparison groups	50 mg Etanercept (ETN) - Induction Period v Placebo - Induction Period
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 8
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI PSO Statistical Analysis 9
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	326
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

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

End point description:

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	86[63]	199[64]	203[65]	211[66]
Units: unit on scale				
least squares mean (standard deviation)				
Work Productivity Loss Score	-2.0 (± 1.80)	-13.7 (± 1.18)	-19.3 (± 1.18)	-19.5 (± 1.18)

Notes:

[63] - All randomized participants who had baseline and at least 1 post baseline work productivity score.

[64] - All randomized participants who had baseline and at least 1 post baseline work productivity score.

[65] - All randomized participants who had baseline and at least 1 post baseline work productivity score.

[66] - All randomized participants who had baseline and at least 1 post baseline work productivity score.

Statistical analyses

Statistical analysis title	WPAI-PSO Statistical Analysis 10
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	285
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 11
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	WPAI-PSO Statistical Analysis 12

Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	158[67]	336[68]	333[69]	344[70]
Units: units on a scale				
least squares mean (standard error)				
Physical Summary Score	-0.4495 (± 0.5226)	2.5498 (± 0.3610)	4.5726 (± 0.3628)	3.7964 (± 0.3575)
Mental Summary Score	-0.0955 (± 0.5886)	2.3221 (± 0.4065)	2.8504 (± 0.4090)	4.5142 (± 0.4026)

Notes:

[67] - All randomized participants who had baseline and at least 1 post baseline SF-36 measurement.

[68] - All randomized participants who had baseline and at least 1 post baseline SF-36 measurement.

[69] - All randomized participants who had baseline and at least 1 post baseline SF-36 measurement.

[70] - All randomized participants who had baseline and at least 1 post baseline SF-36 measurement.

Statistical analyses

Statistical analysis title	SF-36 Statistical Analysis 1

Statistical analysis description:

Physical Summary Score

Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period

Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 2
Statistical analysis description: Physical Summary Score	
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 3
Statistical analysis description: Physical Summary Score	
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	502
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 4
Statistical analysis description: Mental Summary Score	
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 5
Statistical analysis description: Mental Summary Score	
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period

Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	SF-36 Statistical Analysis 6
Statistical analysis description: Mental Summary Score	
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	502
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA

Secondary: Change from baseline in Patient's Global Assessment (PatGA) of Disease Severity

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

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, 12 Weeks

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	164[71]	348[72]	339[73]	343[74]
Units: units on a scale				
least squares mean (standard error)	-0.4 (± 0.09)	-2.1 (± 0.06)	-3.0 (± 0.06)	-3.2 (± 0.06)

Notes:

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

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

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

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

Statistical analyses

Statistical analysis title	PatGA Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	512
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PatGA Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	PatGA Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

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

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

End point description:

The Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. The PPASI was only assessed if participants have palmoplantar psoriasis at baseline. Participants achieving PPASI50, PPASI75 or PASI100 were defined as having an improvement of at least 50%, 75%, or of 100%, respectively, in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data will be considered non-responders.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55[75]	95[76]	102[77]	104[78]
Units: percentage of participants				
number (not applicable)				
PPASI 50	43.6	71.6	85.3	88.5
PPASI 75	30.9	61.1	80.4	79.8
PPASI 100	25.5	50.5	69.6	71.2

Notes:

[75] - All randomized participants who had palmoplantar Ps involvement at baseline.

[76] - All randomized participants who had palmoplantar Ps involvement at baseline.

[77] - All randomized participants who had palmoplantar Ps involvement at baseline.

[78] - All randomized participants who had palmoplantar Ps involvement at baseline.

Statistical analyses

Statistical analysis title	PPASI 50 Statistical Analysis 1
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 50 Statistical Analysis 2
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 50 Statistical Analysis 3
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

	PPASI 75 Statistical Analysis 4

Statistical analysis title	
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 75 Statistical Analysis 5
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 75 Statistical Analysis 6
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 100 Statistical Analysis 7
Comparison groups	Placebo - Induction Period v 50 mg Etanercept (ETN) - Induction Period
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 100 Statistical Analysis 8
Comparison groups	Placebo - Induction Period v Ixe Q4W - Induction Period

Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	PPASI 100 Statistical Analysis 9
Comparison groups	Placebo - Induction Period v Ixe Q2W - Induction Period
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

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 # 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 to Week 12

End point values	Placebo - Induction Period	50 mg Etanercept (ETN) - Induction Period	Ixe Q4W - Induction Period	Ixe Q2W - Induction Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	165[79]	347[80]	340[81]	346[82]
Units: Percentage of Participants				
number (not applicable)	0	2.9	14.1	10.4

Notes:

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

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

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

[82] - All randomized participants who received at least 1 dose of study treatment 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-RHBA

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Placebo - Induction period
Reporting group description: -	
Reporting group title	50 mg ETN - Induction Period
Reporting group description: -	
Reporting group title	Ixe Q4W - Induction period
Reporting group description: -	
Reporting group title	Ixe Q2W - Induction period
Reporting group description: -	
Reporting group title	Ixe/Placebo - Maintenance Period Primary Population
Reporting group description: -	
Reporting group title	Ixe/Ixe Q4W - Maintenance Period Primary Population
Reporting group description: -	
Reporting group title	Ixe/Ixe Q12W - Maintenance Period Primary Population
Reporting group description: -	
Reporting group title	Placebo Resp/Placebo - Maintenance Period Secondary Population
Reporting group description: -	
Reporting group title	Placebo NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Reporting group description: -	
Reporting group title	ETNResp/Placebo - Maintenance Period Secondary Population
Reporting group description: -	
Reporting group title	ETN NonResp/Ixe Q4W - Maintenance Period Secondary Population
Reporting group description: -	
Reporting group title	Ixe Q4W NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Reporting group description: -	
Reporting group title	Ixe Q2W NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Reporting group description: -	
Reporting group title	Ixe Q4W - Maintenance Relapse Population
Reporting group description: -	
Reporting group title	Placebo 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	Placebo Post-Treatment Follow-Up

Reporting group description: -	
Reporting group title	ETN Post-Treatment Follow-Up
Reporting group description: -	
Reporting group title	Ixe Q12W Post-Treatment Follow-Up
Reporting group description: -	
Reporting group title	Ixe Q4W Post-Treatment Follow-Up
Reporting group description: -	
Reporting group title	Ixe Q12W Post-Treatment Follow-Up
Reporting group description: -	

Serious adverse events	Placebo - Induction period	50 mg ETN - Induction Period	Ixe Q4W - Induction period
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 167 (1.80%)	8 / 357 (2.24%)	8 / 347 (2.31%)
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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 119 (0.00%)	0 / 235 (0.00%)	0 / 244 (0.00%)
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 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

peripheral artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
imminent abortion			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 119 (0.00%)	0 / 235 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 119 (0.00%)	0 / 235 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 119 (0.00%)	0 / 235 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 167 (0.60%)	0 / 357 (0.00%)	0 / 347 (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
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[9]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 119 (0.00%)	0 / 235 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (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
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (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

multiple sclerosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 167 (0.60%)	0 / 357 (0.00%)	0 / 347 (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
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 fissure			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 167 (0.60%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (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
stress urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 intestinal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis infective			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

eczema infected			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 pseudomonal alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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 abscess alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhinitis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[12]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ixe Q2W - Induction period	Ixe/Placebo - Maintenance Period Primary Population	Ixe/Ixe Q4W - Maintenance Period Primary Population
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 350 (1.43%)	8 / 176 (4.55%)	12 / 187 (6.42%)
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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 221 (0.00%)	0 / 110 (0.00%)	1 / 131 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyogenic granuloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
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 cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 129 (0.00%)	1 / 66 (1.52%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic dilatation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Surgical and medical procedures			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 221 (0.00%)	0 / 110 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 221 (0.00%)	0 / 110 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 221 (0.00%)	0 / 110 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (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
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 221 (0.00%)	0 / 110 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (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
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal fistula			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (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
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastritis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (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
hypertrophic anal papilla alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 hernia alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
noninfective sialoadenitis alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
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			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (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
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 129 (0.00%)	0 / 66 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 350 (0.29%)	0 / 176 (0.00%)	0 / 187 (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
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
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/Ixe Q12W - Maintenance Period Primary Population	Placebo Resp/Placebo - Maintenance Period	Placebo NonResp/Ixe Q4W - Maintenance Period

		Secondary Population	Secondary Pop
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 181 (7.73%)	0 / 3 (0.00%)	13 / 155 (8.39%)
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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	1 / 120 (0.83%)	0 / 1 (0.00%)	0 / 112 (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
pyogenic granuloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 61 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 120 (0.00%)	0 / 1 (0.00%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 120 (0.00%)	0 / 1 (0.00%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 120 (0.00%)	0 / 1 (0.00%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 120 (0.00%)	0 / 1 (0.00%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
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 ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
lumbar hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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

necrotising fasciitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (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
postoperative wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
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	ETNResp/Placebo - Maintenance Period Secondary	ETN NonResp/Ixe Q4W - Maintenance Period Secondary	Ixe Q4W NonResp/Ixe Q4W - Maintenance Period

	Population	Population	Secondary Pop
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 132 (1.52%)	9 / 200 (4.50%)	4 / 75 (5.33%)
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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (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
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 89 (0.00%)	0 / 126 (0.00%)	0 / 53 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 89 (0.00%)	0 / 126 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 89 (0.00%)	0 / 126 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 89 (0.00%)	0 / 126 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hand fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 89 (0.00%)	0 / 126 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (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
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 132 (0.76%)	0 / 200 (0.00%)	0 / 75 (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
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	0 / 200 (0.00%)	0 / 75 (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
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (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
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
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 Q2W NonResp/Ixe Q4W - Maintenance Period	Ixe Q4W - Maintenance Relapse Population	Placebo Long-Term Extension Period

	Secondary Pop		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 49 (4.08%)	14 / 368 (3.80%)	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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed[1]	0 / 30 (0.00%)	0 / 239 (0.00%)	0 / 14 (0.00%)
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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 19 (0.00%)	0 / 129 (0.00%)	0 / 12 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
aortic stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 19 (0.00%)	0 / 129 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 19 (0.00%)	1 / 129 (0.78%)	0 / 12 (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
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 19 (0.00%)	0 / 129 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 30 (0.00%)	0 / 239 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 30 (0.00%)	0 / 239 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 30 (0.00%)	0 / 239 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	0 / 26 (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
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
schizophrenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
fibula fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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

hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
head injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
joint injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
ligament rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 19 (0.00%)	0 / 129 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 30 (0.00%)	0 / 239 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	0 / 26 (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
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
gastric perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
oesophagitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
pustular psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	1 / 49 (2.04%)	1 / 368 (0.27%)	0 / 26 (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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	0 / 26 (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
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
Infections and infestations			
abscess intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 19 (0.00%)	1 / 129 (0.78%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	1 / 49 (2.04%)	0 / 368 (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
pilonidal cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 19 (0.00%)	0 / 129 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	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
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (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	Placebo Post-Treatment Follow-Up
Total subjects affected by serious			

adverse events			
subjects affected / exposed	107 / 979 (10.93%)	107 / 1002 (10.68%)	1 / 16 (6.25%)
number of deaths (all causes)	4	4	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
colon adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed[1]	3 / 666 (0.45%)	3 / 678 (0.44%)	0 / 10 (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
pyogenic granuloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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

small intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 313 (0.00%)	0 / 324 (0.00%)	0 / 6 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
aortic stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
gallbladder operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 313 (0.00%)	0 / 324 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	1 / 313 (0.32%)	1 / 324 (0.31%)	0 / 6 (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
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 313 (0.00%)	0 / 324 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	1 / 666 (0.15%)	1 / 678 (0.15%)	0 / 10 (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
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	2 / 666 (0.30%)	2 / 678 (0.29%)	0 / 10 (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
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	1 / 666 (0.15%)	1 / 678 (0.15%)	0 / 10 (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
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
schizophrenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Injury, poisoning and procedural complications			
alcohol poisoning			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (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
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
fibula fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hand fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
joint dislocation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
joint injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	1 / 313 (0.32%)	1 / 324 (0.31%)	0 / 6 (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 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
postoperative wound complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Congenital, familial and genetic disorders			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	1 / 666 (0.15%)	1 / 678 (0.15%)	0 / 10 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (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
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (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
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Eye disorders			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
abdominal pain upper			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
lumbar hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
oesophagitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
pustular psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	4 / 979 (0.41%)	4 / 1002 (0.40%)	0 / 16 (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
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Infections and infestations			
abscess intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 313 (0.00%)	0 / 324 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 979 (0.61%)	6 / 1002 (0.60%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	6 / 8	6 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	2 / 3	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	3 / 3	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
peritonsillar abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 979 (0.51%)	5 / 1002 (0.50%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	4 / 5	4 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
postoperative wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
renal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 979 (0.20%)	2 / 1002 (0.20%)	0 / 16 (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
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	1 / 313 (0.32%)	1 / 324 (0.31%)	0 / 6 (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 tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (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 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	0 / 16 (0.00%)
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	ETN Post-Treatment Follow-Up	Ixe Q12W Post-Treatment Follow-Up	Ixe Q4W Post-Treatment Follow-Up
Total subjects affected by serious			

adverse events			
subjects affected / exposed	0 / 6 (0.00%)	3 / 248 (1.21%)	12 / 656 (1.83%)
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)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour benign			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 5 (0.00%)	0 / 170 (0.00%)	0 / 453 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

small intestine adenocarcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transitional cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
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			
aortic aneurysm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic dilatation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic stenosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
circulatory collapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary revascularisation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrectomy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine dilation and curettage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 1 (0.00%)	1 / 78 (1.28%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	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 22.0			
subjects affected / exposed[4]	0 / 1 (0.00%)	0 / 78 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
imminent abortion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
acquired hydrocele			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 5 (0.00%)	0 / 170 (0.00%)	0 / 453 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 5 (0.00%)	0 / 170 (0.00%)	0 / 453 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
penile dysplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 5 (0.00%)	0 / 170 (0.00%)	0 / 453 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus disorder			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
electrocardiogram abnormal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
exposure via father			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hand fracture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint injury alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 fractures			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sternal fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
frenulum breve			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[10]	0 / 5 (0.00%)	0 / 170 (0.00%)	0 / 453 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aortic valve disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
right ventricular failure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus node dysfunction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cognitive disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loss of consciousness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

myelopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
optic ischaemic neuropathy			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
photophobia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 fissure			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticular perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic anal papilla			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
noninfective sialoadenitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal achalasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bile duct stone			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary colic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholestasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
angioedema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythrodermic psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	3 / 656 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 urinary incontinence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 intestinal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess limb			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[11]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

cellulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	0 / 656 (0.00%)
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 staphylococcal			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema infected			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
groin abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis media chronic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhinitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[12]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
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 Q12W Post-Treatment Follow-Up		
Total subjects affected by serious			

adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholesteatoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
colon adenoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
follicular thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
malignant melanoma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
papillary thyroid cancer				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pituitary tumour benign				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostate cancer				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[1]	0 / 14 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyogenic granuloma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
renal cell carcinoma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

small intestine adenocarcinoma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transitional cell carcinoma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tumour embolism				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[2]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
aortic aneurysm				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
aortic dilatation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
aortic stenosis				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
circulatory collapse				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
deep vein thrombosis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
malignant hypertension				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral arterial occlusive disease				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral artery stenosis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
coronary revascularisation				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gallbladder operation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrectomy				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine dilation and curettage				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[3]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
abortion spontaneous				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[4]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
imminent abortion				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[5]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
asthenia				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
death			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
polyp			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypersensitivity				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
acquired hydrocele				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[6]	0 / 14 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
benign prostatic hyperplasia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[7]	0 / 14 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
penile dysplasia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[8]	0 / 14 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
acute respiratory failure				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
asthma				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dyspnoea				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleural effusion				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumothorax				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sinus disorder				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sleep apnoea syndrome				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tonsillar hypertrophy				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
anxiety				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
depression				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
psychotic disorder				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
schizophrenia				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
suicide attempt				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
electrocardiogram abnormal				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
mycobacterium tuberculosis complex test positive				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
weight increased				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
alcohol poisoning				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cervical vertebral fracture				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
concussion				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
exposure via father				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
facial bones fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
femur fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fibula fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

hand fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
head injury				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint dislocation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint injury				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament rupture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
maternal exposure during pregnancy				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[9]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meniscus injury				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
multiple fractures				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
post procedural haemorrhage				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
postoperative wound complication				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rib fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
skin laceration				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

sternal fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tendon rupture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
thoracic vertebral fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tibia fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
frenulum breve				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[10]	0 / 14 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
angina unstable				

alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
aortic valve disease				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrial fibrillation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac arrest				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery disease				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery stenosis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial ischaemia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pericardial effusion				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
right ventricular failure				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sinus node dysfunction				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
carpal tunnel syndrome				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cerebrovascular accident				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cognitive disorder				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
generalised tonic-clonic seizure				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
headache				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ischaemic stroke				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
loss of consciousness				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
multiple sclerosis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

myelopathy				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sciatica				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
syncope				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
vertigo				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
optic ischaemic neuropathy				

alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
photophobia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
abdominal discomfort				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abdominal pain				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abdominal pain upper				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
anal fissure				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
anal fistula				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
colitis ulcerative				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
crohn's disease				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diarrhoea				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticular perforation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
duodenitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastric perforation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

gastritis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypertrophic anal papilla				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
inguinal hernia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lumbar hernia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
noninfective sialoadenitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophageal achalasia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophagitis				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
small intestinal obstruction				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
bile duct obstruction				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bile duct stone				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
biliary colic				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholangitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholecystitis				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholestasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hepatic mass				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
angioedema				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dermatitis allergic				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
erythrodermic psoriasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
psoriasis				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pustular psoriasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rash				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urticaria				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
acute kidney injury				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nephrolithiasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
stress urinary incontinence				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intervertebral disc disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
psoriatic arthropathy				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal pain				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovial cyst				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
abscess intestinal				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abscess limb				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abscess oral				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
appendicitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bartholin's abscess				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[11]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
biliary sepsis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bursitis infective				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

cellulitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis staphylococcal				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholecystitis infective				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
clostridium difficile infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ear infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
eczema infected				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
encephalitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
erysipelas				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis viral				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
groin abscess				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haematoma infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
infectious mononucleosis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

necrotising fasciitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophageal candidiasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
otitis media chronic				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peritonsillar abscess				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pilonidal cyst				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia pseudomonal				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
postoperative wound infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
renal abscess				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rhinitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tonsillitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tubo-ovarian abscess				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[12]	0 / 10 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

urinary tract infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
wound infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
diabetes mellitus				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hyponatraemia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
obesity				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
type 2 diabetes mellitus				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 24 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

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

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

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

Non-serious adverse events	Placebo - Induction period	50 mg ETN - Induction Period	Ixe Q4W - Induction period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 167 (28.74%)	141 / 357 (39.50%)	116 / 347 (33.43%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 167 (0.60%)	0 / 357 (0.00%)	2 / 347 (0.58%)
occurrences (all)	1	0	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 167 (1.20%)	21 / 357 (5.88%)	17 / 347 (4.90%)
occurrences (all)	3	22	21
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	2 / 357 (0.56%)	3 / 347 (0.86%)
occurrences (all)	0	2	3
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 167 (1.20%)	18 / 357 (5.04%)	9 / 347 (2.59%)
occurrences (all)	2	64	10
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 167 (1.20%)	4 / 357 (1.12%)	5 / 347 (1.44%)
occurrences (all)	33	5	33
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 167 (0.60%)	38 / 357 (10.64%)	19 / 347 (5.48%)
occurrences (all)	1	192	30
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[13]	0 / 48 (0.00%)	0 / 122 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 167 (0.60%)	2 / 357 (0.56%)	4 / 347 (1.15%)
occurrences (all)	1	2	4
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 167 (1.80%)	1 / 357 (0.28%)	5 / 347 (1.44%)
occurrences (all)	6	2	6
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	5 / 357 (1.40%)	5 / 347 (1.44%)
occurrences (all)	0	7	5
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 167 (2.99%)	7 / 357 (1.96%)	6 / 347 (1.73%)
occurrences (all)	5	7	6
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 167 (2.99%)	9 / 357 (2.52%)	8 / 347 (2.31%)
occurrences (all)	6	10	10
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	0 / 357 (0.00%)	0 / 347 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 167 (1.80%)	5 / 357 (1.40%)	2 / 347 (0.58%)
occurrences (all)	3	7	2
musculoskeletal chest pain			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	1 / 357 (0.28%)	0 / 347 (0.00%)
occurrences (all)	0	1	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 167 (1.20%)	1 / 357 (0.28%)	2 / 347 (0.58%)
occurrences (all)	2	1	2
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 167 (1.80%)	5 / 357 (1.40%)	4 / 347 (1.15%)
occurrences (all)	3	5	4
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 167 (0.60%)	0 / 357 (0.00%)	2 / 347 (0.58%)
occurrences (all)	1	0	2
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 167 (10.18%)	37 / 357 (10.36%)	28 / 347 (8.07%)
occurrences (all)	21	41	40
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	5 / 357 (1.40%)	5 / 347 (1.44%)
occurrences (all)	0	5	5
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 167 (0.00%)	4 / 357 (1.12%)	6 / 347 (1.73%)
occurrences (all)	0	4	6
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 167 (4.19%)	27 / 357 (7.56%)	16 / 347 (4.61%)
occurrences (all)	8	27	19
urinary tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 167 (1.20%)	2 / 357 (0.56%)	7 / 347 (2.02%)
occurrences (all)	2	2	7
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 48 (0.00%)	1 / 122 (0.82%)	0 / 103 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Ixe Q2W - Induction period	Ixe/Placebo - Maintenance Period Primary Population	Ixe/Ixe Q4W - Maintenance Period Primary Population
Total subjects affected by non-serious adverse events			
subjects affected / exposed	140 / 350 (40.00%)	56 / 176 (31.82%)	100 / 187 (53.48%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	3 / 187 (1.60%)
occurrences (all)	0	0	3
Injury, poisoning and procedural complications			
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 350 (0.86%)	1 / 176 (0.57%)	2 / 187 (1.07%)
occurrences (all)	3	1	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 350 (4.86%)	7 / 176 (3.98%)	12 / 187 (6.42%)
occurrences (all)	23	9	14
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	1 / 187 (0.53%)
occurrences (all)	0	0	1

injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	12 / 350 (3.43%)	2 / 176 (1.14%)	3 / 187 (1.60%)
occurrences (all)	20	3	6
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	13 / 350 (3.71%)	4 / 176 (2.27%)	1 / 187 (0.53%)
occurrences (all)	79	22	3
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	40 / 350 (11.43%)	0 / 176 (0.00%)	15 / 187 (8.02%)
occurrences (all)	76	0	69
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 129 (0.00%)	0 / 66 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 350 (1.71%)	4 / 176 (2.27%)	4 / 187 (2.14%)
occurrences (all)	7	5	4
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 350 (2.00%)	2 / 176 (1.14%)	2 / 187 (1.07%)
occurrences (all)	7	3	2
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 350 (1.43%)	1 / 176 (0.57%)	3 / 187 (1.60%)
occurrences (all)	5	2	3
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	5 / 350 (1.43%)	4 / 176 (2.27%)	3 / 187 (1.60%)
occurrences (all)	5	4	4
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 350 (1.71%)	5 / 176 (2.84%)	8 / 187 (4.28%)
occurrences (all)	6	6	10
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	0 / 176 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 350 (1.14%)	1 / 176 (0.57%)	9 / 187 (4.81%)
occurrences (all)	4	2	10
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 350 (0.57%)	1 / 176 (0.57%)	0 / 187 (0.00%)
occurrences (all)	2	1	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 350 (0.00%)	1 / 176 (0.57%)	1 / 187 (0.53%)
occurrences (all)	0	1	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 350 (1.43%)	3 / 176 (1.70%)	7 / 187 (3.74%)
occurrences (all)	5	3	8
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 350 (0.86%)	0 / 176 (0.00%)	2 / 187 (1.07%)
occurrences (all)	3	0	3
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	34 / 350 (9.71%)	19 / 176 (10.80%)	32 / 187 (17.11%)
occurrences (all)	34	22	42
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 350 (1.14%)	1 / 176 (0.57%)	11 / 187 (5.88%)
occurrences (all)	4	1	12
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 350 (0.57%)	3 / 176 (1.70%)	10 / 187 (5.35%)
occurrences (all)	2	3	10
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	20 / 350 (5.71%)	14 / 176 (7.95%)	25 / 187 (13.37%)
occurrences (all)	21	19	30
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 350 (1.43%)	3 / 176 (1.70%)	5 / 187 (2.67%)
occurrences (all)	5	3	9
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 129 (0.00%)	1 / 66 (1.52%)	0 / 56 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Ixe/Ixe Q12W - Maintenance Period Primary Population	Placebo Resp/Placebo - Maintenance Period Secondary Population	Placebo NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Total subjects affected by non-serious adverse events			
subjects affected / exposed	87 / 181 (48.07%)	2 / 3 (66.67%)	77 / 155 (49.68%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 181 (1.10%)	1 / 3 (33.33%)	1 / 155 (0.65%)
occurrences (all)	2	1	1
Injury, poisoning and procedural complications			

muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 181 (4.42%)	0 / 3 (0.00%)	8 / 155 (5.16%)
occurrences (all)	10	0	14
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 181 (1.10%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences (all)	3	0	1
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 181 (2.21%)	0 / 3 (0.00%)	5 / 155 (3.23%)
occurrences (all)	4	0	14
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences (all)	13	0	5
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 181 (2.21%)	0 / 3 (0.00%)	10 / 155 (6.45%)
occurrences (all)	8	0	42
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[13]	0 / 61 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 181 (3.31%)	0 / 3 (0.00%)	6 / 155 (3.87%)
occurrences (all)	8	0	6
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 181 (2.21%)	0 / 3 (0.00%)	6 / 155 (3.87%)
occurrences (all)	4	0	7
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 181 (2.76%)	0 / 3 (0.00%)	2 / 155 (1.29%)
occurrences (all)	5	0	2
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 181 (2.76%)	0 / 3 (0.00%)	6 / 155 (3.87%)
occurrences (all)	6	0	8
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	10 / 181 (5.52%)	0 / 3 (0.00%)	6 / 155 (3.87%)
occurrences (all)	11	0	7
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	0 / 155 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 181 (3.31%)	0 / 3 (0.00%)	9 / 155 (5.81%)
occurrences (all)	8	0	9
musculoskeletal chest pain			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	1 / 3 (33.33%)	0 / 155 (0.00%)
occurrences (all)	0	1	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 181 (0.00%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	10 / 181 (5.52%)	0 / 3 (0.00%)	2 / 155 (1.29%)
occurrences (all)	12	0	2
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 181 (0.55%)	0 / 3 (0.00%)	1 / 155 (0.65%)
occurrences (all)	1	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	24 / 181 (13.26%)	0 / 3 (0.00%)	29 / 155 (18.71%)
occurrences (all)	31	0	42
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 181 (1.66%)	0 / 3 (0.00%)	3 / 155 (1.94%)
occurrences (all)	3	0	7
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 181 (3.31%)	0 / 3 (0.00%)	7 / 155 (4.52%)
occurrences (all)	6	0	7
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	21 / 181 (11.60%)	0 / 3 (0.00%)	20 / 155 (12.90%)
occurrences (all)	23	0	23
urinary tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	7 / 181 (3.87%)	1 / 3 (33.33%)	8 / 155 (5.16%)
occurrences (all)	9	1	8
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 61 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1

Non-serious adverse events	ETNResp/Placebo - Maintenance Period Secondary Population	ETN NonResp/Ixe Q4W - Maintenance Period Secondary Population	Ixe Q4W NonResp/Ixe Q4W - Maintenance Period Secondary Pop
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 132 (31.82%)	106 / 200 (53.00%)	27 / 75 (36.00%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	1 / 200 (0.50%)	0 / 75 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	1 / 200 (0.50%)	2 / 75 (2.67%)
occurrences (all)	1	1	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 132 (3.79%)	4 / 200 (2.00%)	4 / 75 (5.33%)
occurrences (all)	6	17	4
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences (all)	1	0	0

injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	0 / 200 (0.00%)	0 / 75 (0.00%)
occurrences (all)	3	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	2 / 200 (1.00%)	0 / 75 (0.00%)
occurrences (all)	1	4	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	20 / 200 (10.00%)	3 / 75 (4.00%)
occurrences (all)	3	80	21
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 43 (0.00%)	0 / 74 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	5 / 200 (2.50%)	1 / 75 (1.33%)
occurrences (all)	1	5	1
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 132 (1.52%)	4 / 200 (2.00%)	1 / 75 (1.33%)
occurrences (all)	2	6	1
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	4 / 200 (2.00%)	1 / 75 (1.33%)
occurrences (all)	1	4	1
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 132 (1.52%)	8 / 200 (4.00%)	3 / 75 (4.00%)
occurrences (all)	3	10	5
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 132 (6.06%)	10 / 200 (5.00%)	1 / 75 (1.33%)
occurrences (all)	10	11	1
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	2 / 200 (1.00%)	0 / 75 (0.00%)
occurrences (all)	1	2	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 132 (1.52%)	6 / 200 (3.00%)	3 / 75 (4.00%)
occurrences (all)	7	6	3
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	2 / 200 (1.00%)	0 / 75 (0.00%)
occurrences (all)	0	2	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 132 (2.27%)	1 / 200 (0.50%)	1 / 75 (1.33%)
occurrences (all)	4	1	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	10 / 200 (5.00%)	1 / 75 (1.33%)
occurrences (all)	0	11	1
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	3 / 200 (1.50%)	1 / 75 (1.33%)
occurrences (all)	1	3	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	19 / 132 (14.39%)	35 / 200 (17.50%)	12 / 75 (16.00%)
occurrences (all)	24	47	13
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	7 / 200 (3.50%)	2 / 75 (2.67%)
occurrences (all)	1	7	2
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 132 (0.76%)	7 / 200 (3.50%)	1 / 75 (1.33%)
occurrences (all)	1	7	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 132 (6.06%)	21 / 200 (10.50%)	7 / 75 (9.33%)
occurrences (all)	9	28	10
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 132 (0.00%)	8 / 200 (4.00%)	1 / 75 (1.33%)
occurrences (all)	0	14	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 43 (0.00%)	2 / 74 (2.70%)	2 / 22 (9.09%)
occurrences (all)	0	2	2

Non-serious adverse events	Ixe Q2W NonResp/Ixe Q4W - Maintenance Period Secondary Pop	Ixe Q4W - Maintenance Relapse Population	Placebo Long-Term Extension Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 49 (53.06%)	136 / 368 (36.96%)	7 / 26 (26.92%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	2 / 368 (0.54%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			

muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 49 (8.16%)	12 / 368 (3.26%)	0 / 26 (0.00%)
occurrences (all)	7	19	0
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	0 / 368 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	5 / 368 (1.36%)	0 / 26 (0.00%)
occurrences (all)	0	6	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 49 (2.04%)	1 / 368 (0.27%)	1 / 26 (3.85%)
occurrences (all)	2	1	18
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 49 (4.08%)	19 / 368 (5.16%)	0 / 26 (0.00%)
occurrences (all)	2	62	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[13]	0 / 19 (0.00%)	0 / 129 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 49 (6.12%)	5 / 368 (1.36%)	1 / 26 (3.85%)
occurrences (all)	4	5	1
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 49 (4.08%)	4 / 368 (1.09%)	0 / 26 (0.00%)
occurrences (all)	2	4	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 49 (6.12%)	7 / 368 (1.90%)	0 / 26 (0.00%)
occurrences (all)	4	7	0
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 49 (6.12%)	12 / 368 (3.26%)	1 / 26 (3.85%)
occurrences (all)	3	18	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 49 (2.04%)	13 / 368 (3.53%)	0 / 26 (0.00%)
occurrences (all)	1	14	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	1 / 368 (0.27%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 49 (6.12%)	12 / 368 (3.26%)	1 / 26 (3.85%)
occurrences (all)	3	15	1
musculoskeletal chest pain			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 49 (2.04%)	0 / 368 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 49 (6.12%)	0 / 368 (0.00%)	0 / 26 (0.00%)
occurrences (all)	4	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 49 (4.08%)	11 / 368 (2.99%)	1 / 26 (3.85%)
occurrences (all)	3	11	1
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 49 (2.04%)	1 / 368 (0.27%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 49 (16.33%)	41 / 368 (11.14%)	0 / 26 (0.00%)
occurrences (all)	11	61	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 49 (8.16%)	11 / 368 (2.99%)	0 / 26 (0.00%)
occurrences (all)	5	13	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 49 (0.00%)	12 / 368 (3.26%)	0 / 26 (0.00%)
occurrences (all)	0	12	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 49 (14.29%)	21 / 368 (5.71%)	2 / 26 (7.69%)
occurrences (all)	9	32	4
urinary tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 49 (6.12%)	4 / 368 (1.09%)	1 / 26 (3.85%)
occurrences (all)	3	5	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 19 (0.00%)	1 / 129 (0.78%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Ixe Long-Term Extension Period	Total Ixe Long-Term Extension Period	Placebo Post-Treatment Follow-Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	345 / 979 (35.24%)	345 / 1002 (34.43%)	2 / 16 (12.50%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 979 (0.51%)	5 / 1002 (0.50%)	0 / 16 (0.00%)
occurrences (all)	5	5	0
Injury, poisoning and procedural complications			
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	16 / 979 (1.63%)	16 / 1002 (1.60%)	0 / 16 (0.00%)
occurrences (all)	17	17	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	30 / 979 (3.06%)	30 / 1002 (2.99%)	0 / 16 (0.00%)
occurrences (all)	46	46	0
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 979 (0.00%)	0 / 1002 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (0.00%)
occurrences (all)	3	3	0

injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 979 (0.51%)	5 / 1002 (0.50%)	0 / 16 (0.00%)
occurrences (all)	19	19	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 979 (0.10%)	1 / 1002 (0.10%)	0 / 16 (0.00%)
occurrences (all)	21	21	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	21 / 979 (2.15%)	21 / 1002 (2.10%)	0 / 16 (0.00%)
occurrences (all)	404	404	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	2 / 313 (0.64%)	2 / 324 (0.62%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	20 / 979 (2.04%)	20 / 1002 (2.00%)	0 / 16 (0.00%)
occurrences (all)	21	21	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	11 / 979 (1.12%)	11 / 1002 (1.10%)	0 / 16 (0.00%)
occurrences (all)	11	11	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	12 / 979 (1.23%)	12 / 1002 (1.20%)	0 / 16 (0.00%)
occurrences (all)	15	15	0
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	28 / 979 (2.86%)	28 / 1002 (2.79%)	0 / 16 (0.00%)
occurrences (all)	31	31	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	48 / 979 (4.90%)	48 / 1002 (4.79%)	0 / 16 (0.00%)
occurrences (all)	60	60	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 979 (0.41%)	4 / 1002 (0.40%)	0 / 16 (0.00%)
occurrences (all)	4	4	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	40 / 979 (4.09%)	40 / 1002 (3.99%)	0 / 16 (0.00%)
occurrences (all)	50	50	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 979 (0.31%)	3 / 1002 (0.30%)	0 / 16 (0.00%)
occurrences (all)	3	3	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 979 (0.51%)	5 / 1002 (0.50%)	0 / 16 (0.00%)
occurrences (all)	6	6	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	38 / 979 (3.88%)	38 / 1002 (3.79%)	0 / 16 (0.00%)
occurrences (all)	52	52	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	12 / 979 (1.23%)	12 / 1002 (1.20%)	1 / 16 (6.25%)
occurrences (all)	15	15	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	125 / 979 (12.77%)	125 / 1002 (12.48%)	0 / 16 (0.00%)
occurrences (all)	195	195	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	19 / 979 (1.94%)	19 / 1002 (1.90%)	0 / 16 (0.00%)
occurrences (all)	26	26	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	38 / 979 (3.88%)	38 / 1002 (3.79%)	0 / 16 (0.00%)
occurrences (all)	56	56	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	108 / 979 (11.03%)	108 / 1002 (10.78%)	0 / 16 (0.00%)
occurrences (all)	166	166	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	27 / 979 (2.76%)	27 / 1002 (2.69%)	0 / 16 (0.00%)
occurrences (all)	30	30	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	3 / 313 (0.96%)	3 / 324 (0.93%)	0 / 6 (0.00%)
occurrences (all)	3	3	0

Non-serious adverse events	ETN Post-Treatment Follow-Up	Ixe Q12W Post-Treatment Follow-Up	Ixe Q4W Post-Treatment Follow-Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	21 / 248 (8.47%)	34 / 656 (5.18%)
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	2 / 656 (0.30%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
muscle strain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	0 / 656 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 248 (0.40%)	1 / 656 (0.15%)
occurrences (all)	1	2	1
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	1	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	1	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	0 / 656 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 248 (0.40%)	2 / 656 (0.30%)
occurrences (all)	1	1	2
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	3 / 248 (1.21%)	6 / 656 (0.91%)
occurrences (all)	0	3	6
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	3 / 248 (1.21%)	5 / 656 (0.76%)
occurrences (all)	0	3	5
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	1 / 248 (0.40%)	0 / 656 (0.00%)
occurrences (all)	1	1	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	0 / 656 (0.00%)
occurrences (all)	0	1	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	0 / 656 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	4 / 656 (0.61%)
occurrences (all)	0	0	4
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	3 / 248 (1.21%)	3 / 656 (0.46%)
occurrences (all)	0	3	3
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 6 (16.67%)	3 / 248 (1.21%)	4 / 656 (0.61%)
occurrences (all)	1	3	4
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	3 / 248 (1.21%)	2 / 656 (0.30%)
occurrences (all)	0	4	2
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 248 (0.40%)	3 / 656 (0.46%)
occurrences (all)	0	1	3
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 248 (0.81%)	4 / 656 (0.61%)
occurrences (all)	0	2	4
urinary tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 248 (0.00%)	1 / 656 (0.15%)
occurrences (all)	0	0	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 1 (0.00%)	0 / 78 (0.00%)	0 / 203 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ixe Q12W Post-Treatment Follow-Up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
Investigations			
mycobacterium tuberculosis complex test positive			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
vocal cord paresis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
injection site erythema			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[13]	0 / 10 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[14]	0 / 10 (0.00%)		
occurrences (all)	0		

Notes:

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2012	Changes to protocol (a) are as follows: o Including monthly urine pregnancy testing for women of childbearing potential o Clarifying under "Treatment Assignment for Non-Responders" that patients who have no response. o Removing evaluation of joint pain as a secondary objective o Added a definition of concomitant topical products o Changing the definition of "rebound" to add an evaluation of PASI so that rebound is now defined o Stratifying randomization by center, changing the primary analyses for categorical efficacy outcomes to a Cochran-Mantel-Haenszel (CMH) test stratified by center, specifying the pooling strategy o Using a MMRM approach for the primary analysis of continuous variables o Revised enrollment criteria to exclude participants who are positive for hepatitis B surface antigent or positive for anti- hepatitis B core antibody o Added new exclusion criterion and discontinuation criteria, revised hepatic safety monitoring rules and lab tests, and a discontinuation rule for participants who develop symptoms of lupus-like syndrome
31 October 2012	Changes to protocol (b) are as follows: o Modified exclusion criterion to allow enrollment of patients who have had previous infection with hepatitis B virus (HBV) o Added discontinuation requirement for positive HBV DNA test results o Added section of hepatitis B monitoring o Corrected inclusion criterion to require use of spermicide in conjunction with a diaphragm o Clarified exclusion criterion to define participants with serious cardiac conditions o Clarified descriptions of premedication to indicate that acceptable medications are not restricted to the examples given o Updated the PASI 75 assumption for etanercept at Week 12 to 53%
04 February 2015	Changes to protocol (c) are as follows: o Modified treatment administered in the Long-Term Extension Period o Modified existing text regarding the discontinuation of placebo injections after the study is unblinded o Modified the requirements for discontinuation of inadvertently enrolled participants o Modified permitted concomitant medications o Modified concomitant medications o Modified language on permitted concomitant medication and the permitted drug delivery devices
28 March 2017	Changes to protocol (d) are as follows: Added 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. 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