Clinical trial results:
A Multicenter, Randomized, Double-Blind, Placebo-Controlled 24-Week Study Followed by Long-Term Evaluation of Efficacy and Safety of Ixekizumab (LY2439821) in Biologic Disease-Modifying Antirheumatic Drug-Experienced Patients with Active Psoriatic Arthritis

Summary

EudraCT number	2011-002328-42
Trial protocol	CZ DE ES IT GB
Global end of trial date	26 June 2019

Results information

Result version number	v1 (current)
This version publication date	05 July 2020
First version publication date	05 July 2020

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHBE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02349295
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 14310

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

Global end of trial reached?	Yes
Global end of trial date	26 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate how effective and safe the study drug known as ixekizumab is in participants with active psoriatic arthritis.

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	31 December 2014
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: 20
Country: Number of subjects enrolled	United States: 188
Country: Number of subjects enrolled	Taiwan: 19
Country: Number of subjects enrolled	Poland: 14
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	United Kingdom: 16
Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	France: 17
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Spain: 45
Worldwide total number of subjects	363
EEA total number of subjects	149

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)	301
From 65 to 84 years	61
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Not applicable

Pre-assignment

Screening details:

Not applicable

Period 1

Period 1 title	Double Blind Treatment (Week 0-24)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period

Arm description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 subcutaneous (SC) injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab every 2 Weeks (Q2W) given on Weeks 2, 4, 6, 8, 10, 12,14, 16, 18, 20, 22, and 24.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a starting dose of 160 mg of ixekizumab given as 2 subcutaneous (SC) injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab every 2 Weeks (Q2W) given on Weeks 2, 4, 6, 8, 10, 12,14, 16, 18, 20, 22, and 24.

Arm title	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period

Arm description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14, 18, and 22.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14, 18, and 22.

Arm title	Placebo (PBO) - Blinded Treatment Period

Arm description:

Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24.

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

Dosage and administration details:

Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24.

Number of subjects in period 1	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period	Placebo (PBO) - Blinded Treatment Period
Started	123	122	118
Received Atleast One Dose of Study Drug	123	122	118
Completed	109	111	94
Not completed	14	11	24
Consent withdrawn by subject	2	2	7
Adverse event, non-fatal	7	5	5
Failure To Meet Randomization	-	1	1
Lost to follow-up	1	1	2
Lack of efficacy	4	2	9

Period 2

Period 2 title	IR (Week 16-24)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Ixe 80 mg Q2W - Blinded Treatment Period IR

Arm description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q2W and IR from ixekizumab 80 mg Q2W who continued on ixekizumab 80 mg Q2W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q2W given on Weeks 16, 18, 20, 22, and 24.

Arm type	Experimental

Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q2W and IR from ixekizumab 80 mg Q2W who continued on ixekizumab 80 mg Q2W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q2W given on Weeks 16, 18, 20, 22, and 24.

Arm title	Ixe 80 mg Q4W - Blinded Treatment Period IR

Arm description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q4W and IR from ixekizumab 80 mg Q4W who continued on ixekizumab 80 mg Q4W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q4W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q4W and IR from ixekizumab 80 mg Q4W who continued on ixekizumab 80 mg Q4W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q4W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22.

Arm title	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR

Arm description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q2W for the remainder of the current period and following period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q2W for the remainder of the current period and following period.

Arm title	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR

Arm description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q4W for the remainder of the current period and following period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q4W for the remainder of the current period and following period.

Number of subjects in period 2[1]	Ixe 80 mg Q2W - Blinded Treatment Period IR	Ixe 80 mg Q4W - Blinded Treatment Period IR	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR
Started	17	15	16
Completed	16	15	16
Not completed	1	0	0
Lack of efficacy	1	-	-

Number of subjects in period 2[1]	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR
Started	16
Completed	16
Not completed	0
Lack of efficacy	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Only IR participants were included.

Period 3

Period 3 title	Long-Term Extension Period (Week 24-156)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period

Arm description:

Participants who were randomized to ixekizumab 80 mg Q2W at week 0 and continued on ixekizumab 80 mg Q2W during the Extension Period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who were randomized to ixekizumab 80 mg Q2W at week 0 and continued on ixekizumab 80 mg Q2W during the Extension Period.

Arm title	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period

Arm description:

Participants who were randomized to ixekizumab 80 mg Q4W at week 0 and continued on ixekizumab 80 mg Q4W during the Extension Period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who were randomized to ixekizumab 80 mg Q4W at week 0 and continued on ixekizumab 80 mg Q4W during the Extension Period.

Arm title	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period

Arm description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q2W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q2W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Arm title	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period

Arm description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q4W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	LY2439821
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q4W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Number of subjects in period 3	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period
Started	107	111	46
Completed	55	70	20
Not completed	52	41	26
Adverse event, serious fatal	1	1	1
Unknown/Missing	2	-	3
Consent withdrawn by subject	4	2	1
Physician decision	2	2	-
Adverse event, non-fatal	9	9	2
Lost to follow-up	2	2	-
Lack of efficacy	32	25	19

Number of subjects in period 3	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period
Started	46
Completed	23
Not completed	23
Adverse event, serious fatal	-
Unknown/Missing	-
Consent withdrawn by subject	3
Physician decision	-
Adverse event, non-fatal	2
Lost to follow-up	-
Lack of efficacy	18

Period 4	
Period 4 title	Follow-Up Period (Up to 12-24 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms	
Are arms mutually exclusive?	No

Arm title	Ixe 80 mg Q2W - Post Treatment Follow-Up Period

Arm description:

Participants who received ixekizumab 80 mg Q2W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Ixe 80 mg Q4W - Post Treatment Follow-Up Period

Arm description:

Participants who received ixekizumab 80 mg Q4W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PBO - Post Treatment Follow-Up Period

Arm description:

Participants who received PBO prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	Ixe 80 mg Q2W - Post Treatment Follow-Up Period	Ixe 80 mg Q4W - Post Treatment Follow-Up Period	PBO - Post Treatment Follow-Up Period
Started	142	145	17
Completed	133	137	16
Not completed	9	8	1
Consent withdrawn by subject	1	5	1
Physician decision	2	-	-
Unknown/Missing	4	-	-
Adverse event, non-fatal	1	1	-
Lost to follow-up	1	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period
Reporting group description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 subcutaneous (SC) injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab every 2 Weeks (Q2W) given on Weeks 2, 4, 6, 8, 10, 12,14, 16, 18, 20, 22, and 24.	
Reporting group title	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period
Reporting group description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14, 18, and 22.	
Reporting group title	Placebo (PBO) - Blinded Treatment Period
Reporting group description:	
Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24.	

Reporting group values	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period	Placebo (PBO) - Blinded Treatment Period
Number of subjects	123	122	118
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	51.7	52.6	51.5
standard deviation	± 11.85	± 13.57	± 10.39
Gender categorical Units: Subjects			
Female	73	59	62
Male	50	63	56
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	13	11	11
Not Hispanic or Latino	109	109	106
Unknown or Not Reported	1	2	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	7	7	7
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	1	1
White	113	111	108
More than one race	1	2	2
Unknown or Not Reported	1	0	0
Region of Enrollment			

Units: Subjects			
Czechia	8	4	8
United States	63	65	60
Taiwan	7	6	6
Poland	5	4	5
Italy	1	0	0
United Kingdom	5	6	5
Australia	3	2	2
France	5	6	6
Germany	12	13	11
Spain	14	16	15

Reporting group values	Total		
Number of subjects	363		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	194		
Male	169		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	35		
Not Hispanic or Latino	324		
Unknown or Not Reported	4		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	21		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	3		
White	332		
More than one race	5		
Unknown or Not Reported	1		
Region of Enrollment Units: Subjects			
Czechia	20		
United States	188		
Taiwan	19		
Poland	14		
Italy	1		
United Kingdom	16		
Australia	7		
France	17		
Germany	36		

Spain	45		

End points

End points reporting groups

Reporting group title	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period

Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 subcutaneous (SC) injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab every 2 Weeks (Q2W) given on Weeks 2, 4, 6, 8, 10, 12,14, 16, 18, 20, 22, and 24.

Reporting group title	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period

Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14, 18, and 22.

Reporting group title	Placebo (PBO) - Blinded Treatment Period

Reporting group description:

Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24.

Reporting group title	Ixe 80 mg Q2W - Blinded Treatment Period IR

Reporting group description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q2W and IR from ixekizumab 80 mg Q2W who continued on ixekizumab 80 mg Q2W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q2W given on Weeks 16, 18, 20, 22, and 24.

Reporting group title	Ixe 80 mg Q4W - Blinded Treatment Period IR

Reporting group description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q4W and IR from ixekizumab 80 mg Q4W who continued on ixekizumab 80 mg Q4W. Participants received rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q4W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22.

Reporting group title	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR

Reporting group description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q2W for the remainder of the current period and following period.

Reporting group title	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR

Reporting group description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q4W for the remainder of the current period and following period.

Reporting group title	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period

Reporting group description:

Participants who were randomized to ixekizumab 80 mg Q2W at week 0 and continued on ixekizumab 80 mg Q2W during the Extension Period.

Reporting group title	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period

Reporting group description:

Participants who were randomized to ixekizumab 80 mg Q4W at week 0 and continued on ixekizumab 80 mg Q4W during the Extension Period.

Reporting group title	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period

Reporting group description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q2W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Reporting group title	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period

Reporting group description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q4W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Reporting group title	Ixe 80 mg Q2W - Post Treatment Follow-Up Period

Reporting group description:

Participants who received ixekizumab 80 mg Q2W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	Ixe 80 mg Q4W - Post Treatment Follow-Up Period

Reporting group description:

Participants who received ixekizumab 80 mg Q4W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	PBO - Post Treatment Follow-Up Period

Reporting group description:

Participants who received PBO prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Subject analysis set title	placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12 and 14. Inadequate responders at Week 16 receive rescue therapy and re-randomized (1:1) to either ixekizumab group, receiving a starting dose of 160 mg at Week 16 given as 2 SC injections followed by 80 mg given as 1 injection according to ixekizumab regimen: Q2W or Q4W (with placebo every other dose). All other participants continue placebo as 1 injection Q2W given on Weeks 16, 18, 20 and 22

Subject analysis set title	ixekizumab 80 mg Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14. Inadequate responders at Week 16 receive rescue therapy while continuing ixekizumab given as 1 injection of 80 mg Q4W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22. All other participants continue 80 mg given as 1 injection Q2W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22

Subject analysis set title	ixekizumab 80 mg Q2W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q2W given on Weeks 2, 4, 6, 8, 10, 12 and 14. Inadequate responders at Week 16 receive rescue therapy while continuing ixekizumab given as 1 injection of 80 mg Q2W given on Weeks 16, 18, 20 and 22. All other participants continue 80 mg given as 1 injection Q2W given on Weeks 16, 18, 20 and 22

Primary: Percentage of Participants Achieving American College of Rheumatology 20 Index (ACR20)

End point title	Percentage of Participants Achieving American College of Rheumatology 20 Index (ACR20)

End point description:

ACR20 response is defined as a greater than or equal to (≥) 20% improvement from baseline for tender joint count (TJC) and swollen joint count (SJC) and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain visual analog scale (VAS), Participant's Global Assessment of Disease Activity VAS (PatGA), Physician's Global Assessment of the Disease Activity VAS (PGA), Participant's Assessment of Physical Function using the Health Assessment Questionnaire Disability Index (HAQ-DI), or Acute

Phase Reactant as measured by high sensitivity C-reactive protein (hs-CRP). Analysis population description (APD) included all randomized participants. Non-responder Imputation (NRI) is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Primary

End point timeframe:

Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Percentage of Participants				
number (not applicable)	19.5	53.3	48.0	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	placebo v ixekizumab 80 mg Q4W
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [1]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.65
upper limit	8.48

Notes:

[1] - model includes: treatment, geographic region, and tumor necrosis factor inhibitor (TNFi) experience (inadequate responder to 1 TNFi, inadequate responder to 2 TNFi, or intolerance to a TNFi).

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

model includes: treatment, geographic region, and TNFi experience (inadequate responder to 1 TNFi, inadequate responder to 2 TNFi, or intolerance to a TNFi)

Comparison groups	placebo v ixekizumab 80 mg Q2W
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.12
upper limit	6.78

Notes:

[2] - model includes: treatment, geographic region, and TNFi experience (inadequate responder to 1 TNFi, inadequate responder to 2 TNFi, or intolerance to a TNFi)

Secondary: Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

End point title	Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

End point description:

HAQ-DI is a participant reported questionnaire that measures disease-associated disability(physical function).It consists of 24 questions with 8 domains: dressing/grooming,arising,eating,walking,hygiene,reach,grip and other daily activities.The disability section scores the participant's self-perception on degree of difficulty (0=without any difficulty,1=with some difficulty,2=with much difficulty,3=unable to do covering the 8 domains.HAQ-DI is a composite ranging from 0-3 with lower scores indicating less functional disability.The reported use of special aids/devices and/or the need for assistance of another person to perform these activities is assessed.Least Square (LS) mean calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment,baseline score,geographic region,TNFi experience,visit, treatment-by-visit interaction(itcn), geographic region-by-visit itcn,TNFi experience-by-visit itcn and baseline score-by-visit

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118[3]	122[4]	123[5]	
Units: units on a scale				
least squares mean (standard error)	-0.2 (± 0.08)	-0.6 (± 0.07)	-0.4 (± 0.07)	

Notes:

[3] - APD included all randomized participants.

[4] - APD included all randomized participants.

[5] - APD included all randomized participants.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR20

End point title	Percentage of Participants Achieving ACR20

End point description:

ACR20 response is defined as a ≥20% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:

Week 12

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Percentage of Participants				
number (not applicable)	22.0	50.0	48.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 50 Index (ACR50)

End point title	Percentage of Participants Achieving American College of Rheumatology 50 Index (ACR50)

End point description:

ACR50 response is defined as a ≥50% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:

Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Percentage of Participants				
number (not applicable)	5.1	35.2	33.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 70 Index (ACR70)

End point title	Percentage of Participants Achieving American College of Rheumatology 70 Index (ACR70)

End point description:

ACR70 response is defined as a ≥70% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:

Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Percentage of Participants				
number (not applicable)	0	22.1	12.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Psoriasis Area and Severity Index (PASI) 75

End point title	Percentage of Participants with Psoriasis Area and Severity Index (PASI) 75

End point description:

The PASI is an index that 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 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 75 were defined as having an improvement of at least 75% in the PASI compared to their baseline measures. APD included all randomized participants with baseline psoriatic lesion(s) involving ≥3% body surface area (BSA). NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:

Week 12

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	67	68	68	
Units: Percentage of Participants				
number (not applicable)	10.4	57.4	61.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of patients achieving Minimal disease activity (MDA)

End point title	Percentage of patients achieving Minimal disease activity (MDA)

End point description:

It uses a composite of 7 key outcome measures (includes PASI) used in PsA to encompass all of the domains of the disease to measure the overall state of a patients' disease. The LEI is used to assess tender entheseal points. Patients are classified as achieving MDA if they fulfill 5 of 7 outcome measures: 1. TJC ≤1, 2. SJC ≤1, 3. PASI total score ≤1 or BSA ≤3, 4. patient pain VAS score of ≤15, 5. patient global VAS score of ≤20, 6. HAQ-DI score ≤0.5, 7. tender entheseal points (6 entheseal points) ≤1. APD included all randomized participants. NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:

Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Percentage of Participants				
number (not applicable)	3.4	27.9	23.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of patients achieving complete resolution in enthesitis as assessed by the Leeds Enthesitis Index (LEI)

End point title	Percentage of patients achieving complete resolution in enthesitis as assessed by the Leeds Enthesitis Index (LEI)

End point description:

The LEI was developed specifically for use in PsA. It measures enthesitis at 6 sites (lateral epicondyle, left and right; medial femoral condyle, left and right; Achilles tendon insertion, left and right). Each site was assigned a score of 0 (absent) or 1 (present); the results from each site were then added to produce a total score (range 0 to 6). So, "0" indicates good score here. APD included all randomized participants who had baseline enthesitis, baseline LEI score and post baseline LEI score data. NRI is applied for inadequate responders at Week 16 and participants who had missing data at Week 24 for any reason including discontinuation.

End point type	Secondary

End point timeframe:
Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	69	68	84	
Units: Percentage of Participants				
number (not applicable)	21.7	35.3	31.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Itch Numeric Rating Scale (NRS)

End point title	Change from Baseline in Itch Numeric Rating Scale (NRS)

End point description:

The Itch 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." Overall severity of a participants itching from psoriasis was indicated by circling the number that best described the worst level of itching in the past 24 hours. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants who had baseline psoriatic lesion(s) involving >=3% BSA, baseline itch NRS score and post baseline itch NRS score data.

End point type	Secondary

End point timeframe:
Baseline, Week 12

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-0.7 (± 0.40)	-3.4 (± 0.39)	-3.3 (± 0.39)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Tender Joint Count (TJC)

End point title	Change from Baseline in Tender Joint Count (TJC)

End point description:

TJC is the number of tender and painful joints determined for each participant by examination of 68 joints. Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions. Any positive response on pressure, movement, or both was translated into a single tender-versus-nontender dichotomy. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline TJC data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Tender Joint Count				
least squares mean (standard error)	-6.2 (± 1.96)	-12.7 (± 1.87)	-12.5 (± 1.77)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Swollen Joint Count (SJC)

End point title	Change from Baseline in Swollen Joint Count (SJC)

End point description:

SJC is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline SJC data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Swollen Joint Count				
least squares mean (standard error)	-5.0 (± 1.05)	-8.5 (± 0.99)	-7.4 (± 0.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Participants Assessment of Pain Visual Analog Scale (VAS)

End point title	Change from Baseline in Participants Assessment of Pain Visual Analog Scale (VAS)

End point description:

The pain VAS is a participant-administered single-item scale designed to measure current joint pain from Psoriatic arthritis (PsA) using a 100-millimeter(mm) horizontal VAS. Overall severity of participant's joint pain from PsA is indicated by marking a vertical tick on the horizontal 100-mm scale, where the left end from 0 mm (no pain) to right end 100 mm (worst possible joint pain). LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline TJC and SJC data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-21.4 (± 3.97)	-36.9 (± 3.74)	-33.5 (± 3.58)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Patients Global Assessment of Disease Activity VAS

End point title	Change from Baseline in Patients Global Assessment of Disease Activity VAS

End point description:

The patient’s overall assessment of his or her PsA activity will be recorded using a 100-mm horizontal VAS, where 0 represents no disease activity and 100 represents extremely active disease. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline Patients Global Assessment of Disease Activity VAS score.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-19.0 (± 3.91)	-40.7 (± 3.68)	-37.3 (± 3.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physicians Global Assessment of Disease Activity VAS

End point title	Change from Baseline in Physicians Global Assessment of Disease Activity VAS

End point description:

The investigator will be asked to give an overall assessment of the severity of the participant's current PsA activity using a 100-mm horizontal VAS, where 0 represents no disease activity and 100 represents extremely active disease. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline Physicians Global Assessment of Disease Activity VAS score.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-18.3 (± 3.98)	-40.0 (± 3.85)	-37.9 (± 3.75)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in C-Reactive Protein (CRP)

End point title	Change from Baseline in C-Reactive Protein (CRP)

End point description:

C-reactive protein (CRP) is a disease related biomarker and measured in milligrams per liter. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants with baseline and post baseline CRP data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: milligram per liter (mg/L)				
least squares mean (standard error)	-3.6 (± 1.87)	-11.8 (± 1.76)	-9.8 (± 1.68)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Disease Activity Score-CRP (DAS28-CRP)

End point title	Change from Baseline in Disease Activity Score-CRP (DAS28-CRP)

End point description:

The DAS28-CRP is a measure of disease activity in 28 joints that consists of a composite numerical score with the following variables: TJC28, SJC28, hs-CRP (measured in mg/L), and Participant's Global Assessment of Disease Activity recorded by participants on a 0 to 100 millimeter (mm) VAS. For DAS28-CRP, the Tender Joint Count 28 (TJC28) and Swollen Joint Count (SJC28) are a subset of TJC and SJC, and include 14 joints on each side of the body: 2 shoulders, 2 elbows, 2 wrists, 10 metacarpophalangeal joints, the 2 interphalangeal joints of the thumb, the 8 proximal interphalangeal joints, and the 2 knees. DAS28 values range from 0 to 9.4. Higher values indicate more severe symptoms and greater functional impairment. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118[6]	122[7]	123[8]	
Units: Units on a Scale				
least squares mean (standard error)	-0.8 (± 0.20)	-2.1 (± 0.19)	-1.8 (± 0.18)	

Notes:

[6] - APD included all randomized participants who had baseline and post baseline DAS28-CRP data.

[7] - APD included all randomized participants who had baseline and post baseline DAS28-CRP data.

[8] - APD included all randomized participants who had baseline and post baseline DAS28-CRP data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score

End point title	Change from Baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score

End point description:

The BASDAI is a self-administered measure used to answer 6 questions with a 0 to 10 centimeter (cm) VAS pertaining to the 5 major symptoms of axial activity. To give each symptom equal weighting, the mean of the 2 scores relating to morning stiffness was taken. The resulting 0 to 50 score was divided by 5 to give a final 0 to 10 BASDAI Score. BASDAI ranges from 0-10. Higher scores represent greater disease activity. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants who had baseline axial involvement defined as baseline BASDAI score >4, baseline BASDAI score and post baseline BASDAI score data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-2.1 (± 0.38)	-3.7 (± 0.36)	-3.6 (± 0.35)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fatigue Severity Numeric Rating Scale (NRS) Score

End point title	Change from Baseline in Fatigue Severity Numeric Rating Scale (NRS) Score

End point description:

The Fatigue Severity NRS is a participant-administered single-item 11-point horizontal scale anchored at 0 and 10, with 0 representing "no fatigue" and 10 representing "as bad as you can imagine." Participants rated their fatigue (feeling tired or worn out) by circling the 1 number that described their worst level of fatigue during the past 24 hours. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants who had baseline and post baseline fatigue NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	-0.7 (± 0.37)	-2.0 (± 0.35)	-2.1 (± 0.34)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in 36-Item Short-Form Health Survey (SF-36) Scores: Physical Component Summary (PCS)

End point title	Change from Baseline in 36-Item Short-Form Health Survey (SF-36) Scores: Physical Component Summary (PCS)

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 was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants who had baseline and post baseline PCS data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	3.3 (± 1.36)	8.9 (± 1.29)	8.2 (± 1.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in 36-Item Short-Form Health Survey (SF-36) Scores: Mental Component Summary (MCS)

End point title	Change from Baseline in 36-Item Short-Form Health Survey (SF-36) Scores: 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 was calculated using MMRM analysis with treatment, baseline score, geographic region, TNFi experience, visit, treatment-by-visit interaction, geographic region-by-visit interaction, TNFi experience-by-visit interaction, and baseline score-by-visit interaction. APD included all randomized participants who had baseline and post baseline MCS data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	122	123	
Units: Units on a Scale				
least squares mean (standard error)	0.9 (± 1.32)	3.6 (± 1.24)	4.0 (± 1.18)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment Emergent Anti-Drug Antibodies (TE-ADA)

End point title	Number of Participants With Treatment Emergent Anti-Drug Antibodies (TE-ADA)

End point description:

Number of participants with positive treatment emergent anti-ixekizumab antibodies was summarized by treatment group. APD included all randomized participants who received at least 1 dose of ixekizumab and had evaluable anti-ixekizumab antibody measurement.

End point type	Secondary

End point timeframe:

Week 24

End point values	placebo	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	112	117	120	
Units: Participants				
number (not applicable)	1	8	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK):Minimum Observed Serum Concentration at Steady State (Ctrough,ss) of Ixekizumab

End point title	Pharmacokinetics (PK):Minimum Observed Serum Concentration at Steady State (Ctrough,ss) of Ixekizumab

End point description:

The Ctrough is the minimum observed serum concentration at steady state of Ixekizumab. The Ctrough at Week 24 was reported. APD included all enrolled participants who received at least one dose of the study drug and had evaluable ixekizumab PK data.

End point type	Secondary

End point timeframe:

All immunogenicity samples post the first Ixekizumab dose (Week 4, 12, 24, 36, and 52) and PK samples collected per dedicated sparse sampling plan (4-5 samples per patient) across Weeks 1 through 24 and Early termination visit (ETV)

End point values	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	102	101		
Units: micrograms per milliliter (mcg/mL)				
geometric mean (geometric coefficient of variation)	2.46 (± 79.1)	7.96 (± 71.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics: Area Under the Concentration-Time Curve for Dosing Interval (Tau) at Steady State [AUC(Tau,Steady State)] of Ixekizumab

End point title	Pharmacokinetics: Area Under the Concentration-Time Curve for Dosing Interval (Tau) at Steady State [AUC(Tau,Steady State)] of Ixekizumab

End point description:

The AUC(Tau,Steady State) is the area under the concentration-time curve for dosing interval (Tau) at steady state of ixekizumab (Tau is 28 days for 80 mg Q4W cohort, and is 14 days for 80mg Q2W cohort, respectively). APD included all enrolled participants who received at least one dose of the study drug and had evaluable ixekizumab PK data.

End point type	Secondary

End point timeframe:

All immunogenicity samples post the first Ixekizumab dose (Week 4, 12, 24, 36, and 52) and PK samples collected per dedicated sparse sampling plan (4-5 samples per patient) across Weeks 1 through 24 and Early termination visit (ETV)

End point values	ixekizumab 80 mg Q4W	ixekizumab 80 mg Q2W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	105	100		
Units: mcg*day/mL				
geometric mean (geometric coefficient of variation)	141 (± 59.3)	143 (± 57.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR 20

End point title	Percentage of Participants Achieving ACR 20

End point description:

ACR20 response is defined as a ≥20% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. Non-responder Imputation (NRI) is applied for inadequate responders at week 16 and participants who discontinued on or prior to week 24.

End point type	Secondary

End point timeframe:

Week 52 and Week 156

End point values	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	111	46	46
Units: Percentage of participants				
number (not applicable)				
Week 52	58.9	67.6	50.0	60.9
Week 156	42.1	50.5	39.1	45.7

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR 50

End point title	Percentage of Participants Achieving ACR 50

End point description:

ACR50 response is defined as a ≥50% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's

Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. Non-responder Imputation (NRI) is applied for inadequate responders at week 16 and participants who discontinued on or prior to week 24.

End point type	Secondary

End point timeframe:

Week 52 and Week 156

End point values	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	111	46	46
Units: Percentage of participants				
number (not applicable)				
Week 52	38.3	45.9	34.8	43.5
Week 156	29.0	35.1	26.1	34.8

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR 70

End point title	Percentage of Participants Achieving ACR 70

End point description:

ACR70 response is defined as a ≥70% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of Joint Pain VAS, Participant's Global Assessment of Disease Activity VAS, Physician's Global Assessment of the Disease Activity VAS, Participant's Assessment of Physical Function using the HAQ-DI, or hs-CRP. APD included all randomized participants. Non-responder Imputation (NRI) is applied for inadequate responders at week 16 and participants who discontinued on or prior to week 24.

End point type	Secondary

End point timeframe:

Week 52 and Week 156

End point values	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	111	46	46
Units: Percentage of participants				
number (not applicable)				
Week 52	20.6	28.8	15.2	23.9

Week 156	22.4	21.6	10.9	19.6

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 2.55 Years

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug. The gender specific events only occurring in male or female participants were adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period

Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 subcutaneous (SC) injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab every 2 Weeks (Q2W) given on Weeks 2, 4, 6, 8, 10, 12,14, 16, 18, 20, 22, and 24.

Reporting group title	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period

Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections at Week 0 followed by 1 SC injection of 80 mg of ixekizumab Q4W given on Weeks 4, 8 and 12 alternating with placebo for ixekizumab injections Q4W given on Weeks 2, 6, 10 and 14, 18, and 22.

Reporting group title	Placebo (PBO) - Blinded Treatment Period

Reporting group description:

Participants received placebo for ixekizumab as 2 SC injections followed by 1 SC injection Q2W given on Weeks 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24.

Reporting group title	Ixe 80 mg Q2W - Blinded Treatment Period IR

Reporting group description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q2W and IR from ixekizumab 80 mg Q2W who continued on ixekizumab 80 mg Q2W. Patients receive rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q2W given on Weeks 16, 18, 20, 22, and 24.

Reporting group title	Ixe 80 mg Q4W - Blinded Treatment Period IR

Reporting group description:

Week 16 inadequate responders from the placebo treatment group who were re-randomized (1:1) to ixekizumab 80 mg Q4W and IR from ixekizumab 80 mg Q4W who continued on ixekizumab 80 mg Q4W. Patients receive rescue therapy while receiving ixekizumab given as 1 injection of 80 mg Q4W given on Weeks 16 and 20 alternating with placebo for ixekizumab injections Q4W given on Weeks 18 and 22.

Reporting group title	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR

Reporting group description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q2W for the remainder of the current period and following period.

Reporting group title	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR

Reporting group description:

Participants initially randomized to placebo treatment group in the double blind treatment period who were flagged as inadequate responders at week 16 were re-randomized to ixekizumab 80 mg Q4W for the remainder of the current period and following period.

Reporting group title	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period

Reporting group description:

Participants who were randomized to ixekizumab 80 mg Q2W at week 0 and continued on ixekizumab 80 mg Q2W during the Extension Period.

Reporting group title	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period

Reporting group description:

Participants who were randomized to ixekizumab 80 mg Q4W at week 0 and continued on ixekizumab 80 mg Q4W during the Extension Period.

Reporting group title	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period

Reporting group description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q2W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Reporting group title	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period

Reporting group description:

Participants who were randomized to placebo at Week 0 then randomized to ixekizumab 80 mg Q4W during the Extension Period.
Participants who remained on placebo at the completion of the double blind treatment period received the first dose of ixekizumab (160 mg starting dose) at Week 24.
Participants who were IRs at Week 16 and were re-randomized to ixekizumab at Week 16 received the first dose of ixekizumab (160 mg starting dose) at Week 16.

Reporting group title	Ixe 80 mg Q2W - Post Treatment Follow-Up Period

Reporting group description:

Participants who received ixekizumab 80 mg Q2W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	Ixe 80 mg Q4W - Post Treatment Follow-Up Period

Reporting group description:

Participants who received ixekizumab 80 mg Q4W prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Reporting group title	PBO - Post Treatment Follow-Up Period

Reporting group description:

Participants who received PBO prior to entering the post-treatment follow-up period, who were either completed the study or discontinued the study early entered the post-treatment follow-up period (a 12-24 week period after their last scheduled treatment visit).

Serious adverse events	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period	Placebo (PBO) - Blinded Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 123 (6.50%)	3 / 122 (2.46%)	4 / 118 (3.39%)
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)			
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 in situ			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 50 (0.00%)	1 / 63 (1.59%)	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			
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary arterial stent insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee arthroplasty			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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[2]	1 / 73 (1.37%)	0 / 59 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
adnexa uteri cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 73 (0.00%)	0 / 59 (0.00%)	1 / 62 (1.61%)
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 prolapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	1 / 73 (1.37%)	0 / 59 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchospasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic stroke			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal fistula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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
colitis ischaemic			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 cirrhosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
basedow's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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			
myofascial pain syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 jaw			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
latent tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oral candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

osteomyelitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
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 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (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

Serious adverse events	Ixe 80 mg Q2W - Blinded Treatment Period IR	Ixe 80 mg Q4W - Blinded Treatment Period IR	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 in situ			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
metastatic renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 / 17 (0.00%)	0 / 15 (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
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Surgical and medical procedures			
coronary arterial stent insertion			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
knee arthroplasty			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 12 (0.00%)	0 / 6 (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
Reproductive system and breast disorders			
adnexa uteri cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 12 (0.00%)	0 / 6 (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
uterine prolapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 12 (0.00%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
bronchospasm			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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			
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
femoral neck fracture			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
foot fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
postoperative wound complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
coronary artery thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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			
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
haemorrhagic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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	0 / 17 (0.00%)	0 / 15 (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
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 / 17 (0.00%)	0 / 15 (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 ischaemic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 / 17 (0.00%)	0 / 15 (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
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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

Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 cirrhosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Endocrine disorders			
basedow's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 and connective tissue disorders			
myofascial pain syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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

Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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	0 / 17 (0.00%)	0 / 15 (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
latent tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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 candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
oral candidiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
osteomyelitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
perirectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
postoperative wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (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	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 16 (6.25%)	10 / 107 (9.35%)	13 / 111 (11.71%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
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 melanoma in situ			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 9 (0.00%)	0 / 46 (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
Vascular disorders			
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 arterial stent insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee arthroplasty			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 7 (0.00%)	0 / 61 (0.00%)	0 / 55 (0.00%)
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			
adnexa uteri cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 7 (0.00%)	0 / 61 (0.00%)	0 / 55 (0.00%)
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 prolapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 7 (0.00%)	0 / 61 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchospasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
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			
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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			
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	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	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
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 infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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			
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ischaemic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	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	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 cirrhosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
basedow's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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			
myofascial pain syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
latent tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oral candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
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	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period	Ixe 80 mg Q2W - Post Treatment Follow-Up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 46 (13.04%)	3 / 46 (6.52%)	1 / 142 (0.70%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma in situ			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[1]	0 / 22 (0.00%)	0 / 20 (0.00%)	0 / 64 (0.00%)
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			
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
coronary arterial stent insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
knee arthroplasty			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 22 (0.00%)	0 / 26 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
adnexa uteri cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 22 (0.00%)	0 / 26 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine prolapse			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 22 (0.00%)	0 / 26 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchospasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (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
Injury, poisoning and procedural complications			

ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
coronary artery thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal fistula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ischaemic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (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
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (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
nausea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic cirrhosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
basedow's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
myofascial pain syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (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
latent tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oral candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ixe 80 mg Q4W - Post Treatment Follow-Up Period	PBO - Post Treatment Follow-Up Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 145 (1.38%)	2 / 17 (11.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma in situ			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastatic renal cell carcinoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
papillary thyroid cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 72 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
coronary arterial stent insertion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
knee arthroplasty			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 73 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
adnexa uteri cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 73 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

uterine prolapse			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 73 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchospasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
ankle fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral neck fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
foot fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative wound complication			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardio-respiratory arrest			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery thrombosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervicobrachial syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhagic stroke			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal fistula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis ischaemic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cirrhosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
basedow's disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
myofascial pain syndrome			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
latent tuberculosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oral candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
perirectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

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

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

Non-serious adverse events	Ixekizumab 80 mg Q2W (Ixe 80 mg Q2W)- Blinded Treatment Period	Ixekizumab 80 mg Q4W (Ixe 80 mg Q4W)- Blinded Treatment Period	Placebo (PBO) - Blinded Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 123 (47.15%)	58 / 122 (47.54%)	40 / 118 (33.90%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 123 (4.88%)	2 / 122 (1.64%)	3 / 118 (2.54%)
occurrences (all)	6	3	3
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
injection site erythema			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 123 (3.25%)	3 / 122 (2.46%)	0 / 118 (0.00%)
occurrences (all)	20	4	0
injection site induration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences (all)	1	1	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 123 (1.63%)	1 / 122 (0.82%)	2 / 118 (1.69%)
occurrences (all)	6	1	4
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	15 / 123 (12.20%)	6 / 122 (4.92%)	1 / 118 (0.85%)
occurrences (all)	47	20	1
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 123 (1.63%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences (all)	15	1	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	1 / 50 (2.00%)	0 / 63 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 123 (3.25%)	4 / 122 (3.28%)	3 / 118 (2.54%)
occurrences (all)	5	5	3
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	7 / 122 (5.74%)	0 / 118 (0.00%)
occurrences (all)	1	7	0
Psychiatric disorders			

sleep terror			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 123 (1.63%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	2	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
exposure to toxic agent			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
lymphadenopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
entropion			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dental caries			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences (all)	1	0	1
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
mouth ulceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences (all)	1	0	1
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 123 (2.44%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	3	0	0
erythema			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 123 (0.81%)	3 / 122 (2.46%)	0 / 118 (0.00%)
occurrences (all)	1	3	0
night sweats			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
pruritus generalised			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	1 / 118 (0.85%)
occurrences (all)	0	1	1
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	5 / 122 (4.10%)	2 / 118 (1.69%)
occurrences (all)	1	5	2
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	0 / 122 (0.00%)	2 / 118 (1.69%)
occurrences (all)	1	0	2
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 123 (2.44%)	3 / 122 (2.46%)	8 / 118 (6.78%)
occurrences (all)	3	3	8
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 123 (2.44%)	1 / 122 (0.82%)	4 / 118 (3.39%)
occurrences (all)	3	2	4
cystitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	0 / 122 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 123 (0.81%)	2 / 122 (1.64%)	1 / 118 (0.85%)
occurrences (all)	1	2	2
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 123 (3.25%)	9 / 122 (7.38%)	4 / 118 (3.39%)
occurrences (all)	4	11	4
otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	2 / 122 (1.64%)	0 / 118 (0.00%)
occurrences (all)	0	2	0
otitis media			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 123 (1.63%)	1 / 122 (0.82%)	1 / 118 (0.85%)
occurrences (all)	2	1	1
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	2 / 122 (1.64%)	1 / 118 (0.85%)
occurrences (all)	0	2	1
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 123 (4.07%)	7 / 122 (5.74%)	2 / 118 (1.69%)
occurrences (all)	7	7	2
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	4 / 122 (3.28%)	0 / 118 (0.00%)
occurrences (all)	0	4	0

upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	12 / 123 (9.76%)	12 / 122 (9.84%)	9 / 118 (7.63%)
occurrences (all)	12	14	12
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 123 (3.25%)	6 / 122 (4.92%)	3 / 118 (2.54%)
occurrences (all)	4	11	3
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	2 / 73 (2.74%)	0 / 59 (0.00%)	0 / 62 (0.00%)
occurrences (all)	2	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	2 / 73 (2.74%)	1 / 59 (1.69%)	1 / 62 (1.61%)
occurrences (all)	2	1	1
Metabolism and nutrition disorders			
hyperuricaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 123 (0.00%)	1 / 122 (0.82%)	0 / 118 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Ixe 80 mg Q2W - Blinded Treatment Period IR	Ixe 80 mg Q4W - Blinded Treatment Period IR	PBO IR / Ixe 80 mg Q2W - Blinded Treatment Period IR
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 17 (29.41%)	8 / 15 (53.33%)	11 / 16 (68.75%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2

influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	2 / 16 (12.50%)
occurrences (all)	2	0	2
injection site induration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 17 (11.76%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	3
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 17 (11.76%)	1 / 15 (6.67%)	2 / 16 (12.50%)
occurrences (all)	3	2	2
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1

oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
sleep terror			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
exposure to toxic agent			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
lymphadenopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
thrombocytopenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
entropion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
dental caries			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

alopecia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
night sweats			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
pruritus generalised			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 17 (5.88%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
otitis media			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hyperuricaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 17 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PBO IR / Ixe 80 mg Q4W - Blinded Treatment Period IR	Ixe 80 mg Q2W / Ixe 80 mg Q2W - Extended Treatment Period	Ixe 80 mg Q4W / Ixe 80 mg Q4W - Extended Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 16 (50.00%)	59 / 107 (55.14%)	65 / 111 (58.56%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	3 / 107 (2.80%)	3 / 111 (2.70%)
occurrences (all)	0	3	3
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences (all)	2	0	1
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences (all)	0	11	0
injection site induration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	3 / 107 (2.80%)	0 / 111 (0.00%)
occurrences (all)	0	7	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	6 / 107 (5.61%)	2 / 111 (1.80%)
occurrences (all)	2	92	39
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	3 / 107 (2.80%)	1 / 111 (0.90%)
occurrences (all)	2	46	1
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[5]	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 56 (1.79%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	4 / 107 (3.74%)	6 / 111 (5.41%)
occurrences (all)	0	4	6
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	2 / 107 (1.87%)	2 / 111 (1.80%)
occurrences (all)	0	2	3
Psychiatric disorders			
sleep terror			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	2 / 107 (1.87%)	1 / 111 (0.90%)
occurrences (all)	1	2	1
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	4 / 111 (3.60%)
occurrences (all)	0	1	4
Injury, poisoning and procedural complications			
exposure to toxic agent			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

lymphadenopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	2 / 107 (1.87%)	0 / 111 (0.00%)
occurrences (all)	0	2	0
thrombocytopenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Eye disorders			
entropion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dental caries			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	2 / 107 (1.87%)	1 / 111 (0.90%)
occurrences (all)	2	2	2
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	2 / 107 (1.87%)	1 / 111 (0.90%)
occurrences (all)	0	2	1
mouth ulceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	1 / 107 (0.93%)	3 / 111 (2.70%)
occurrences (all)	1	1	3
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3
erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
night sweats			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	2
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	5 / 107 (4.67%)	8 / 111 (7.21%)
occurrences (all)	0	5	9
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	3 / 111 (2.70%)
occurrences (all)	0	1	3

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	3 / 107 (2.80%)	1 / 111 (0.90%)
occurrences (all)	0	6	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	11 / 107 (10.28%)	11 / 111 (9.91%)
occurrences (all)	1	12	13
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	3
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	4 / 107 (3.74%)	2 / 111 (1.80%)
occurrences (all)	0	4	2
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	15 / 107 (14.02%)	20 / 111 (18.02%)
occurrences (all)	0	26	32
otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	2 / 107 (1.87%)	0 / 111 (0.00%)
occurrences (all)	0	2	0
otitis media			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 107 (0.93%)	5 / 111 (4.50%)
occurrences (all)	0	1	6
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	10 / 107 (9.35%)	11 / 111 (9.91%)
occurrences (all)	1	14	13
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	3 / 107 (2.80%)	4 / 111 (3.60%)
occurrences (all)	0	3	4
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	20 / 107 (18.69%)	15 / 111 (13.51%)
occurrences (all)	0	33	23
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 16 (0.00%)	6 / 107 (5.61%)	7 / 111 (6.31%)
occurrences (all)	0	13	8
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 7 (0.00%)	0 / 61 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 7 (0.00%)	2 / 61 (3.28%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
hyperuricaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Placebo/ Ixe 80 mg Q2W - Extended Treatment Period	Placebo/ Ixe 80 mg Q4W - Extended Treatment Period	Ixe 80 mg Q2W - Post Treatment Follow-Up Period
Total subjects affected by non-serious adverse events			

subjects affected / exposed	20 / 46 (43.48%)	32 / 46 (69.57%)	16 / 142 (11.27%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	3 / 46 (6.52%)	0 / 142 (0.00%)
occurrences (all)	1	3	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	0	4	0
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	1	1	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 46 (8.70%)	5 / 46 (10.87%)	0 / 142 (0.00%)
occurrences (all)	7	5	0
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	0	15	0

Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	1 / 24 (4.17%)	3 / 20 (15.00%)	0 / 64 (0.00%)
occurrences (all)	1	3	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	1 / 142 (0.70%)
occurrences (all)	0	1	1
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
sleep terror			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	1 / 142 (0.70%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			

exposure to toxic agent			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
lymphadenopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	0	1	0
thrombocytopenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
entropion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dental caries			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	4 / 46 (8.70%)	0 / 142 (0.00%)
occurrences (all)	0	5	0
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	3 / 46 (6.52%)	0 / 142 (0.00%)
occurrences (all)	1	3	0
mouth ulceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
rectal haemorrhage			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	3 / 46 (6.52%)	0 / 142 (0.00%)
occurrences (all)	0	3	0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	1	0	0
erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	0	1	0
night sweats			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	3 / 46 (6.52%)	1 / 142 (0.70%)
occurrences (all)	0	3	1

muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 46 (0.00%)	1 / 142 (0.70%)
occurrences (all)	3	0	1
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	1 / 46 (2.17%)	1 / 142 (0.70%)
occurrences (all)	1	4	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	2 / 46 (4.35%)	1 / 142 (0.70%)
occurrences (all)	1	4	1
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	2 / 46 (4.35%)	0 / 142 (0.00%)
occurrences (all)	0	2	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	1 / 46 (2.17%)	0 / 142 (0.00%)
occurrences (all)	3	3	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	3	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 46 (13.04%)	4 / 46 (8.70%)	3 / 142 (2.11%)
occurrences (all)	11	6	4
otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	3 / 46 (6.52%)	1 / 142 (0.70%)
occurrences (all)	1	3	1
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 46 (8.70%)	6 / 46 (13.04%)	3 / 142 (2.11%)
occurrences (all)	4	6	3
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	2 / 46 (4.35%)	0 / 142 (0.00%)
occurrences (all)	1	3	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 46 (8.70%)	8 / 46 (17.39%)	2 / 142 (1.41%)
occurrences (all)	7	9	2
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	5 / 46 (10.87%)	2 / 142 (1.41%)
occurrences (all)	1	9	3
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 22 (0.00%)	1 / 26 (3.85%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 22 (0.00%)	2 / 26 (7.69%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
hyperuricaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 46 (2.17%)	0 / 46 (0.00%)	0 / 142 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Ixe 80 mg Q4W - Post Treatment Follow-Up Period	PBO - Post Treatment Follow-Up Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 145 (8.97%)	2 / 17 (11.76%)	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
injection site induration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
injection site reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 72 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
sleep terror			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
blood bilirubin increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
hepatic enzyme increased			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
exposure to toxic agent			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
lymphadenopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
thrombocytopenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
entropion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
dental caries			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	

mouth ulceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
rectal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
night sweats			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
pruritus generalised			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue			

disorders			
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 145 (4.14%)	0 / 17 (0.00%)	
occurrences (all)	6	0	
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 145 (3.45%)	0 / 17 (0.00%)	
occurrences (all)	5	0	
otitis externa			

alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)		
occurrences (all)	0	0		
otitis media				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)		
occurrences (all)	0	0		
respiratory tract infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)		
occurrences (all)	1	0		
sinusitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)		
occurrences (all)	0	0		
tonsillitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)		
occurrences (all)	1	0		
upper respiratory tract infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 145 (0.69%)	0 / 17 (0.00%)		
occurrences (all)	1	0		
urinary tract infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 145 (0.00%)	2 / 17 (11.76%)		
occurrences (all)	0	2		
vulvovaginal candidiasis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed[6]	0 / 73 (0.00%)	0 / 8 (0.00%)		
occurrences (all)	0	0		
vulvovaginal mycotic infection				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed[7]	0 / 73 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
hyperuricaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 145 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	

Notes:

[5] - 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: The gender specific events only occurring in male or female participants were adjusted accordingly.
[6] - 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: The gender specific events only occurring in male or female participants were adjusted accordingly.
[7] - 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: The gender specific events only occurring in male or female participants were adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported