



Clinical trial results:

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

Summary

EudraCT number	2011-002326-49
Trial protocol	CZ GB BE EE BG ES NL
Global end of trial date	22 September 2017

Results information

Result version number	v1 (current)
This version publication date	30 September 2018
First version publication date	30 September 2018

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHAP
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01695239
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13731

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 September 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will assess the safety and efficacy of ixekizumab (LY2439821) compared to placebo 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	01 December 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Russian Federation: 34
Country: Number of subjects enrolled	United States: 83
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Ukraine: 35
Country: Number of subjects enrolled	United Kingdom: 16
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Czech Republic: 92
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Poland: 60
Country: Number of subjects enrolled	Mexico: 12
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Bulgaria: 16
Country: Number of subjects enrolled	Estonia: 29
Worldwide total number of subjects	416
EEA total number of subjects	236

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)	372
From 65 to 84 years	44
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Entered

Pre-assignment

Screening details:

Participants were randomized to treatment at Week 0 and entered the Double-Blind Treatment Period (Week 0 up to Week 24). Inadequate Responders (IR) were identified at Week 16. The combined extension period and long-term extension period occurred from Week 24 to Week 156.

Period 1

Period 1 title	Double-Blind (DB) Treatment Period
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	Placebo (PBO)

Arm description:

Participants received placebo for ixekizumab (ixe) as 2 subcutaneous (SC) injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections every 2 weeks (Q2W) from Week 2 to Week 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 (ixe) as 2 subcutaneous (SC) injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections every 2 weeks (Q2W) from Week 2 to Week 24.

Arm title	Adalimumab (ADA) Q2W
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Arm description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

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

Dosage and administration details:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Arm title	Ixekizumab (Ixe) Q4W
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Arm description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Arm type	Experimental
Investigational medicinal product name	ixekizumab
Investigational medicinal product code	
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 of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Arm title	Ixe Q2W
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Arm description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Arm type	Experimental
Investigational medicinal product name	ixekizumab
Investigational medicinal product code	
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 of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Number of subjects in period 1	Placebo (PBO)	Adalimumab (ADA) Q2W	Ixekizumab (Ixe) Q4W
Started	106	101	107
Received at least 1 dose of study drug	106	101	107
Classified as Inadequate Responder (IR)	27 ^[1]	9 ^[2]	11 ^[3]
Completed	91	97	97
Not completed	15	4	10
Consent withdrawn by subject	3	1	1
On Study Treatment	-	-	1
Adverse event, non-fatal	2	2	2
Sponsor Decision	3	-	1
Lost to follow-up	1	-	-
Entry Criteria Not Met	1	1	3
Lack of efficacy	4	-	2
Protocol deviation	1	-	-

Number of subjects in period 1	Ixe Q2W
Started	103
Received at least 1 dose of study drug	102
Classified as Inadequate Responder (IR)	10 ^[4]
Completed	96
Not completed	7
Consent withdrawn by subject	-
On Study Treatment	-
Adverse event, non-fatal	3
Sponsor Decision	-
Lost to follow-up	-
Entry Criteria Not Met	4
Lack of efficacy	-
Protocol deviation	-

Notes:

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

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

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

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

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

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

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

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

Period 2

Period 2 title	IR Participants (Week 16 Up To Week 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?	No
Arm title	Inadequate Responders (IR)/Ixe Q4W

Arm description:

Placebo Week 16 inadequate responders (IRs) re-randomized to ixekizumab 80 mg every 4 weeks (Q4W) received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 16. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy. Ixekizumab Q4W IRs received one SC injection of 80 mg of ixekizumab or

placebo for ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab 80 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants continuing on 1 injection of ixekizumab 80 mg Q4W starting on Week 24 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 28 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 32 and ending on Week 156 alternating with placebo injections Q4W starting on Week 34 and ending on Week 154.

Arm title	IR/Ixe Q2W
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Arm description:

Placebo IRs re-randomized to ixekizumab 80 mg Q2W received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 16. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy. Ixekizumab 80 mg Q2W IRs received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab 80 mg Q4W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo IRs re-randomized to ixekizumab 80 mg Q2W received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 16. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy. Ixekizumab 80 mg Q2W IRs received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy.

Arm title	IR PBO Washout
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Arm description:

Adalimumab Q2W IRs re-randomized to ixekizumab 80 mg Q4W or ixekizumab 80 mg Q2W. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 16. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 18 to Week 22. Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 24.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab 80 mg Q4W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab Q2W IRs re-randomized to ixekizumab 80 mg Q4W or ixekizumab 80 mg Q2W. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 16. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 18 to Week 22. Participants received a starting dose of 160 mg of

ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 24.

Number of subjects in period 2	Inadequate Responders (IR)/Ixe Q4W	IR/Ixe Q2W	IR PBO Washout
Started	24	24	9
Completed	24	24	9

Period 3

Period 3 title	Placebo Washout (Week 24 Up To Week 32)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Treatment remained blinded to investigators, study site personnel, and participants until participants have completed Week 24 or have discontinued from the study (moved into Period 5) and the clinical trial database through Week 24 has been locked. Thus, to maintain blinding, each participant will continue to receive 1 dose Q2W of investigational product regardless of his/her assigned treatment group (that is, placebo for ixekizumab was given every other week to maintain blinding).

Arms

Arm title	PBO Washout
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Arm description:

Adalimumab Q2W participants re-randomized to ixekizumab 80 mg Q4W or ixekizumab Q2W Week 24. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 24. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 26 to Week 30. Participants received a dose of 80 mg of ixekizumab given as 1 SC injection at Week 32.

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

Dosage and administration details:

Adalimumab Q2W participants re-randomized to ixekizumab 80 mg Q4W or ixekizumab Q2W Week 24. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 24. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 26 to Week 30. Participants received a dose of 80 mg of ixekizumab given as 1 SC injection at Week 32.

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

Dosage and administration details:

Adalimumab Q2W participants re-randomized to ixekizumab 80 mg Q4W or ixekizumab Q2W Week 24. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 24. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 26 to Week 30. Participants received a dose of 80 mg of ixekizumab given as 1 SC injection at Week 32.

Number of subjects in period 3	PBO Washout
Started	88
Completed	77
Not completed	11
Adverse event, non-fatal	1
Entry Criteria Not Met	1
Lack of efficacy	9

Period 4

Period 4 title	Extension Long-Term Extension Periods
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Treatment remained blinded to investigators, study site personnel, and participants until participants have completed Week 24 or have discontinued from the study (moved into Period 5) and the clinical trial database through Week 24 has been locked. Thus, to maintain blinding, each participant will continue to receive 1 dose Q2W of investigational product regardless of his/her assigned treatment group (that is, placebo for ixekizumab was given every other week to maintain blinding).

Arms

Are arms mutually exclusive?	No
Arm title	Ixe Q4W/Ixe Q4W

Arm description:

Participants continuing on 1 injection of ixekizumab 80 mg Q4W starting on Week 24 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 28 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 32 and ending on Week 156 alternating with placebo injections Q4W starting on Week 34 and ending on Week 154.

Arm type	Experimental
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Investigational medicinal product name	Ixekizumab 80 mg Q4W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants continuing on 1 injection of ixekizumab 80 mg Q4W starting on Week 24 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 28 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 32 and ending on Week 156 alternating with placebo injections Q4W starting on Week 34 and ending on Week 154.

Arm title	Ixe Q2W/Ixe Q2W
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Arm description:

Participants continuing on 1 injection of ixekizumab 80 mg Q2W starting on Week 24 and ending on Week 156. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg Q2W at Week 16 and Week 24. Placebo washout participants who re-randomized at Week 16 receive a starting dose of 160 mg ixekizumab given as 2 SC injections of 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 28 and ending on Week 156. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 32 and ending on Week 156.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab 80 mg Q2W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants continuing on 1 injection of ixekizumab 80 mg Q2W starting on Week 24 and ending on Week 156. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg Q2W at Week 16 and Week 24. Placebo washout participants who re-randomized at Week 16 receive a starting dose of 160 mg ixekizumab given as 2 SC injections of 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 28 and ending on Week 156. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 32 and ending on Week 156.

Number of subjects in period 4	Ixe Q4W/Ixe Q4W	Ixe Q2W/Ixe Q2W
Started	187	183
Completed	121	122
Not completed	66	61
Adverse event, serious fatal	1	-
Consent withdrawn by subject	6	7
Physician decision	3	-
Adverse event, non-fatal	15	21
Sponsor Decision	2	1
Lost to follow-up	2	1
Lack of efficacy	37	31

Period 5

Period 5 title	Post-Treatment Follow-Up Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Treatment remained blinded to investigators, study site personnel, and participants until participants have completed Week 24 or have discontinued from the study (moved into Period 5) and the clinical trial database through Week 24 has been locked. Thus, to maintain blinding, each participant will continue to receive 1 dose Q2W of investigational product regardless of his/her assigned treatment group (that is, placebo for ixekizumab was given every other week to maintain blinding).

Arms

Are arms mutually exclusive?	No
Arm title	Placebo Post-Treatment Follow-up Period

Arm description: -

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 discontinued the study early and entered the post-treatment follow-up period. Participants received placebo immediately prior to entering the post-treatment follow-up period.

Arm title	Adalimumab Post-Treatment Follow-up Period
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Arm description:

Participants discontinued the study early and entered the post-treatment follow-up period. Participants received adalimumab Q2W immediately prior to entering the post-treatment follow-up period.

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

Dosage and administration details:

Participants discontinued the study early and entered the post-treatment follow-up period. Participants received adalimumab Q2W immediately prior to entering the post-treatment follow-up period.

Arm title	Ixekizumab 80mg Q4W Post-Treatment Follow-up Period
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Arm description:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q4W immediately prior to entering the post-treatment follow-up period.

Arm type	Active comparator
Investigational medicinal product name	Ixekizumab 80 mg Q4W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q4W immediately prior to entering the post-treatment follow-up period.

Arm title	Ixekizumab 80mg Q2W Post-Treatment Follow-up Period
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Arm description:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q2W immediately prior to entering the post-treatment follow-up period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab 80 mg Q2W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q2W immediately prior to entering the post-treatment follow-up period.

Number of subjects in period 5	Placebo Post-Treatment Follow-up Period	Adalimumab Post-Treatment Follow-up Period	Ixekizumab 80mg Q4W Post-Treatment Follow-up Period
Started	20	1	165
Completed	20	1	156
Not completed	0	0	9
Consent withdrawn by subject	-	-	6
Physician decision	-	-	2
Lost to follow-up	-	-	1
Protocol deviation	-	-	-

Number of subjects in period 5	Ixekizumab 80mg Q2W Post-Treatment Follow-up Period
Started	171
Completed	166
Not completed	5
Consent withdrawn by subject	3
Physician decision	-
Lost to follow-up	1
Protocol deviation	1

Period 6

Period 6 title	Baseline Period
Is this the baseline period?	Yes ^[5]
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

All participants who were enrolled in the study at baseline less 1 participant who did not have age data, was not part of safety evaluation and did not take any dose.

Arms

Arm title	All participants
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Arm description:

Total number of participants enrolled at baseline

Arm type	No treatment received
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 (ixe) as 2 subcutaneous (SC) injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections every 2 weeks (Q2W) from Week 2 to Week 24.

Investigational medicinal product name	Adalimumab (ADA) Q2W
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Investigational medicinal product name	Ixe Q4W
Investigational medicinal product code	
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 of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Investigational medicinal product name	Ixe Q2W
Investigational medicinal product code	
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 of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received

one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Notes:

[5] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1, the double-blind treatment period start number is based on the number of participants enrolled prior to receiving a dose of drug. The selected baseline period includes all the participants enrolled and received drug less 1 participant that did not have documented age data.

Number of subjects in period 6	All participants
Started	416
Completed	416

Baseline characteristics

Reporting groups

Reporting group title	Baseline Period
Reporting group description: -	

Reporting group values	Baseline Period	Total	
Number of subjects	416	416	
Age categorical			
1 participant didn't have age data, was not part of safety evaluation and did not take any dose.			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age Continuous			
Units: years			
arithmetic mean	49.52		
standard deviation	± 11.87	-	
Gender, Male/Female			
Units: Participants			
Female	225	225	
Male	191	191	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	9	9	
Asian	15	15	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	391	391	
More than one race	1	1	
Unknown or Not Reported	0	0	
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	20	20	
Not Hispanic or Latino	355	355	
Unknown or Not Reported	41	41	
Region of Enrollment			
Units: Subjects			
Russia	34	34	
United States	83	83	
Japan	12	12	

Ukraine	35	35	
United Kingdom	16	16	
Spain	13	13	
Canada	4	4	
Czechia	92	92	
Netherlands	2	2	
Belgium	5	5	
Poland	60	60	
Mexico	12	12	
France	3	3	
Bulgaria	16	16	
Estonia	29	29	

End points

End points reporting groups

Reporting group title	Placebo (PBO)
Reporting group description: Participants received placebo for ixekizumab (ixe) as 2 subcutaneous (SC) injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections every 2 weeks (Q2W) from Week 2 to Week 24.	
Reporting group title	Adalimumab (ADA) Q2W
Reporting group description: Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Reporting group title	Ixekizumab (Ixe) Q4W
Reporting group description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Reporting group title	Ixe Q2W
Reporting group description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Reporting group title	Inadequate Responders (IR)/Ixe Q4W
Reporting group description: Placebo Week 16 inadequate responders (IRs) re-randomized to ixekizumab 80 mg every 4 weeks (Q4W) received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 16. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy. Ixekizumab Q4W IRs received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy.	
Reporting group title	IR/Ixe Q2W
Reporting group description: Placebo IRs re-randomized to ixekizumab 80 mg Q2W received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 16. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy. Ixekizumab 80 mg Q2W IRs received one SC injection of 80 mg of ixekizumab Q2W from Week 18 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 18 to Week 24. Participants also received rescue therapy.	
Reporting group title	IR PBO Washout
Reporting group description: Adalimumab Q2W IRs re-randomized to ixekizumab 80 mg Q4W or ixekizumab 80 mg Q2W. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 16. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 18 to Week 22. Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 24.	
Reporting group title	PBO Washout
Reporting group description: Adalimumab Q2W participants re-randomized to ixekizumab 80 mg Q4W or ixekizumab Q2W Week 24. Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 24. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 26 to Week 30. Participants received a dose of 80 mg of ixekizumab given as 1 SC injection at Week 32.	

Reporting group title	Ixe Q4W/Ixe Q4W
Reporting group description:	
Participants continuing on 1 injection of ixekizumab 80 mg Q4W starting on Week 24 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 28 and ending on Week 156 alternating with placebo injections Q4W starting on Week 26 and ending on Week 154. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q4W starting on Week 32 and ending on Week 156 alternating with placebo injections Q4W starting on Week 34 and ending on Week 154.	
Reporting group title	Ixe Q2W/Ixe Q2W
Reporting group description:	
Participants continuing on 1 injection of ixekizumab 80 mg Q2W starting on Week 24 and ending on Week 156. Additionally, includes placebo washout participants who were re-randomized to ixekizumab 80 mg Q2W at Week 16 and Week 24. Placebo washout participants who re-randomized at Week 16 receive a starting dose of 160 mg ixekizumab given as 2 SC injections of 80 mg given at Week 24 followed by 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 28 and ending on Week 156. Placebo washout participants who re-randomized at Week 24 receive 1 SC injection of 80 mg of ixekizumab Q2W starting on Week 32 and ending on Week 156.	
Reporting group title	Placebo Post-Treatment Follow-up Period
Reporting group description: -	
Reporting group title	Adalimumab Post-Treatment Follow-up Period
Reporting group description:	
Participants discontinued the study early and entered the post-treatment follow-up period. Participants received adalimumab Q2W immediately prior to entering the post-treatment follow-up period.	
Reporting group title	Ixekizumab 80mg Q4W Post-Treatment Follow-up Period
Reporting group description:	
Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q4W immediately prior to entering the post-treatment follow-up period.	
Reporting group title	Ixekizumab 80mg Q2W Post-Treatment Follow-up Period
Reporting group description:	
Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q2W immediately prior to entering the post-treatment follow-up period.	
Reporting group title	All participants
Reporting group description:	
Total number of participants enrolled at baseline	
Subject analysis set title	Double-Blind PBO
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	Double-Blind ADA Q2W
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Double-Blind Ixe Q4W
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Double-Blind Ixe Q2W
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.

Subject analysis set title	ADA Q2W
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q4W
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q2W
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Subject analysis set title	Placebo
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Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	

Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.	
Subject analysis set title	ADA Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.	
Subject analysis set title	Ixe Q2W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC	

injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Subject analysis set title	Ixe Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

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

Subject analysis set description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC

Primary: Percentage of Participants Achieving American College of Rheumatology 20 (ACR20) Response at Week 24 (Efficacy of ixekizumab in participants with active psoriatic arthritis. Measure: American College of Rheumatology 20 Index [ACR20])

End point title	Percentage of Participants Achieving American College of Rheumatology 20 (ACR20) Response at Week 24 (Efficacy of ixekizumab in participants with active psoriatic arthritis. Measure: American College of Rheumatology 20 Index [ACR20])
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End point description:

ACR20 response is defined as a $\geq 20\%$ 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).

End point type	Primary
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End point timeframe:

Week 24

End point values	Placebo (PBO)	Adalimumab (ADA) Q2W	Ixekizumab (Ixe) Q4W	Ixe Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106 ^[1]	101 ^[2]	107 ^[3]	103 ^[4]
Units: percentage of participants				
number (not applicable)	30	57	58	62

Notes:

- [1] - Nonresponder Imputation (NRI) is applied for Inadequate Responders (IR) who had missing data.
- [2] - All randomized participants. NRI is applied for IR and participants who had missing data.
- [3] - All randomized participants. NRI is applied for IR and participants who had missing data.
- [4] - the 1 participant didn't have age data, was not part of safety evaluation and did not take any dose.

Statistical analyses

Statistical analysis title	ACR20 Additional Statistical Analysis
Comparison groups	Placebo (PBO) v Adalimumab (ADA) Q2W
Number of subjects included in analysis	207
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic

Statistical analysis title	ACR20 Additional Statistical Analysis
Comparison groups	Placebo (PBO) v Ixekizumab (Ixe) Q4W

Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic

Statistical analysis title	ACR20 Additional Statistical Analysis
Comparison groups	Placebo (PBO) v Ixe Q2W
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic

Secondary: Percentage of Participants Achieving ACR20 Response

End point title	Percentage of Participants Achieving ACR20 Response
End point description: ACR20 response is defined as a $\geq 20\%$ 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.	
End point type	Secondary
End point timeframe: Week 12	

End point values	Placebo (PBO)	Adalimumab (ADA) Q2W	Ixekizumab (Ixe) Q4W	Ixe Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106 ^[5]	101 ^[6]	107 ^[7]	103 ^[8]
Units: percentage of participants				
number (not applicable)	31	52	57	60

Notes:

[5] - All randomized participants. NRI is applied for IR and participants who had missing data.

[6] - All randomized participants. NRI is applied for IR and participants who had missing data.

[7] - All randomized participants. NRI is applied for IR and participants who had missing data.

[8] - All randomized participants. NRI is applied for IR and participants who had missing data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving American College of Rheumatology 50 (ACR50) Response

End point title	Percentage of Participants achieving American College of Rheumatology 50 (ACR50) Response
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End point description:

ACR50 response is defined as a $\geq 50\%$ 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.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo (PBO)	Adalimumab (ADA) Q2W	Ixekizumab (Ixe) Q4W	Ixe Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106 ^[9]	101 ^[10]	107 ^[11]	103 ^[12]
Units: percentage of participants				
number (not applicable)	15	39	40	47

Notes:

[9] - All randomized participants. NRI is applied for IR and participants who had missing data.

[10] - All randomized participants. NRI is applied for IR and participants who had missing data.

[11] - All randomized participants. NRI is applied for IR and participants who had missing data.

[12] - All randomized participants. NRI is applied for IR and participants who had missing data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving American College of Rheumatology 70 (ACR70) Score

End point title	Percentage of Participants achieving American College of Rheumatology 70 (ACR70) Score
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End point description:

ACR70 response is defined as a $\geq 70\%$ 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.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo (PBO)	Adalimumab (ADA) Q2W	Ixekizumab (Ixe) Q4W	Ixe Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106 ^[13]	101 ^[14]	107 ^[15]	103 ^[16]
Units: percentage of participants				
number (not applicable)	6	26	23	34

Notes:

[13] - All randomized participants. NRI is applied for IR and participants who had missing data.

[14] - All randomized participants. NRI is applied for IR and participants who had missing data.

[15] - All randomized participants. NRI is applied for IR and participants who had missing data.

[16] - All randomized participants. NRI is applied for IR and participants who had missing data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Scores (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])

End point title	Change from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Scores (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])
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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 the degree of difficulty (0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty, and 3 = unable to do), covering the 8 domains. The HAQ-DI is a composite ranging from 0-3 with lower scores indicating less functional disability. The reported use of special aids or devices and/or the need for assistance of another person to perform these activities is assessed. Least Square (LS) mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline score, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	105 ^[17]	97 ^[18]	103 ^[19]	98 ^[20]
Units: units on a scale				
least squares mean (standard error)	-0.1797 (± 0.0524)	-0.3712 (± 0.0510)	-0.4431 (± 0.0503)	-0.4963 (± 0.0507)

Notes:

[17] - All randomized participants with baseline and post baseline HAQ-DI data.

[18] - All randomized participants with baseline and post baseline HAQ-DI data.

[19] - All randomized participants with baseline and post baseline HAQ-DI data.

[20] - All randomized participants with baseline and post baseline HAQ-DI data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Modified Total Sharp Score (mTSS) (Efficacy of ixekizumab in participants with active psoriatic arthritis. Measure: modified Total Sharp Score [mTSS])

End point title	Change from Baseline in Modified Total Sharp Score (mTSS) (Efficacy of ixekizumab in participants with active psoriatic arthritis. Measure: modified Total Sharp Score [mTSS])
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End point description:

The mTSS measures the extent of bone erosions (20 joints per hand and 12 joints per foot) and joint space narrowing (20 joints per hand and 6 joints per foot), with higher scores representing greater damage. An increase from baseline represents disease progression and / or joint worsening. Scores range from 0-528. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, and baseline cDMARD experience, visit, treatment by visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[21]	101 ^[22]	107 ^[23]	103 ^[24]
Units: units on a scale				
least squares mean (standard error)	0.49 (± 0.086)	0.10 (± 0.085)	0.17 (± 0.082)	0.08 (± 0.083)

Notes:

[21] - All randomized participants with baseline and post baseline mTSS data.

[22] - All randomized participants with baseline and post baseline mTSS data.

[23] - All randomized participants with baseline and post baseline mTSS data.

[24] - All randomized participants with baseline and post baseline mTSS data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Psoriasis Area and Severity Index 75%, 90%, 100% (PASI 75, 90, 100)

End point title	Percentage of Participants Achieving Psoriasis Area and Severity Index 75%, 90%, 100% (PASI 75, 90, 100)
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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. Participants achieving PASI 90 were defined as having an improvement of $\geq 90\%$ in the PASI score compared to baseline. Participants achieving PASI 100 were defined as having an improvement of 100% in the PASI score compared to baseline.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67 ^[25]	68 ^[26]	73 ^[27]	59 ^[28]
Units: percentage of participants				
number (not applicable)				
PASI 75	8	34	75	70
PASI 90	2	22	52	58

PASI 100	2	15	32	41
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Notes:

[25] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[26] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[27] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[28] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Leeds Enthesitis Index (LEI)

End point title	Change from baseline in Leeds Enthesitis Index (LEI)
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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). LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, treatment by visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	57 ^[29]	55 ^[30]	70 ^[31]	56 ^[32]
Units: units on a scale				
least squares mean (standard error)	-0.8 (\pm 0.24)	-0.8 (\pm 0.24)	-0.9 (\pm 0.21)	-1.5 (\pm 0.24)

Notes:

[29] - All randomized participants with baseline enthesitis, LEI score, and post baseline LEI score.

[30] - All randomized participants with baseline enthesitis, LEI score, and post baseline LEI score.

[31] - All randomized participants with baseline enthesitis, LEI score, and post baseline LEI score.

[32] - All randomized participants with baseline enthesitis, LEI score, and post baseline LEI score.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in itching severity using the Itch Numeric Rating Scale (NRS) (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])

End point title	Change from baseline in itching severity using the Itch Numeric Rating Scale (NRS) (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])
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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 participant's 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, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67 ^[33]	68 ^[34]	73 ^[35]	59 ^[36]
Units: units on a scale				
least squares mean (standard error)	0.2 (± 0.27)	-1.4 (± 0.28)	-2.6 (± 0.27)	-2.8 (± 0.30)

Notes:

[33] - All randomized participants who had baseline psoriatic lesion(s) involving $\geq 3\%$ BSA.

[34] - All randomized participants who had baseline psoriatic lesion(s) involving $\geq 3\%$ BSA.

[35] - All randomized participants who had baseline psoriatic lesion(s) involving $\geq 3\%$ BSA.

[36] - All randomized participants who had baseline psoriatic lesion(s) involving $\geq 3\%$ BSA.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fatigue Severity NRS Score (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])

End point title	Change From Baseline in Fatigue Severity NRS Score (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])
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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, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	ADA Q2W	Placebo	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	97 ^[37]	103 ^[38]	101 ^[39]	97 ^[40]
Units: units on a scale				
least squares mean (standard error)	-1.5 (± 0.24)	-1.3 (± 0.25)	-1.6 (± 0.24)	-1.9 (± 0.24)

Notes:

[37] - All randomized participants who had baseline and post baseline fatigue NRS data.

[38] - All randomized participants who had baseline and post baseline fatigue NRS data.

[39] - All randomized participants who had baseline and post baseline fatigue NRS data.

[40] - All randomized participants who had baseline and post baseline fatigue NRS data.

Statistical analyses

Secondary: Change from Baseline in Joint Space Narrowing Score (JSN) And Bone Erosion Score (BES)

End point title	Change from Baseline in Joint Space Narrowing Score (JSN) And Bone Erosion Score (BES)
End point description:	
JSN score (a component of the modified Total Sharp Score [mTSS]) measures the extent of joint space narrowing in peripheral joints. JSN (20 joints per hand and 6 joints per foot), with higher scores representing greater damage. JSN score range is 0 (no narrowing) to 208 (high narrowing). Increase from baseline represents disease progression and / or joint worsening. BES (a component of the [mTSS]) measures the extent of bone erosion in peripheral joints. BES measures the extent of joint erosions (20 joints per hand and 12 joints per foot), with higher scores representing greater damage. Erosion score range is from 0 (no erosion) to 320 (high erosion). LS mean was calculated using linear extrapolation for ANCOVA analysis with treatment, baseline score, geographic region, and baseline cDMARD experience.	
End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	91 ^[41]	95 ^[42]	97 ^[43]	96 ^[44]
Units: units on a scale				
least squares mean (standard error)				
Joint Space Narrowing Score	0.07 (± 0.031)	0.01 (± 0.031)	0.04 (± 0.030)	0.01 (± 0.030)
Bone Erosion Score	0.44 (± 0.077)	0.12 (± 0.077)	0.15 (± 0.075)	0.08 (± 0.075)

Notes:

[41] - All randomized participants who had baseline and post baseline JSN data.

[42] - All randomized participants who had baseline and post baseline JSN data.

[43] - All randomized participants who had baseline and post baseline JSN data.

[44] - All randomized participants who had baseline and post baseline JSN data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Medical Outcomes Study 36-item Short Form Health Survey (SF-36): Physical Component Summary (PCS) and Mental Component Summary (MCS) (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])

End point title	Change From Baseline in Medical Outcomes Study 36-item Short Form Health Survey (SF-36): Physical Component Summary (PCS) and Mental Component Summary (MCS) (Quality of Life and Outcome Assessments Measures: Participant Reported Outcomes [PRO])
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End point description:

SF-36 is a standardized participant-administered measure designed to evaluate 8 domains of functional health and well being: physical and social functioning, physical and emotional role (role-physical, role-emotional) limitations, bodily pain, general health, vitality, mental health with 2 components (physical component score [PCS] and mental component score [MCS]). The PCS and MCS scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	ADA Q2W	Placebo	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	95 ^[45]	99 ^[46]	98 ^[47]	95 ^[48]
Units: units on a scale				
least squares mean (standard error)				
PCS Score	6.78 (± 0.904)	2.94 (± 0.958)	7.45 (± 0.894)	8.24 (± 0.898)
MCS Score	4.22 (± 0.943)	2.67 (± 1.013)	4.86 (± 0.933)	3.39 (± 0.936)

Notes:

[45] - All randomized participants who had baseline and post baseline PCS data.

[46] - All randomized participants who had baseline and post baseline PCS data.

[47] - All randomized participants who had baseline and post baseline PCS data.

[48] - All randomized participants who had baseline and post baseline PCS data.

Statistical analyses

No statistical analyses for this end point

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

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

The QIDS-SR16 is a self-administered 16-item instrument intended to assess the existence and severity of symptoms of depression. A participant is asked to consider each statement as it relates to the way they have felt for the past 7 days. Each item scaled from 0 (no symptoms) to 3 (all symptoms). The 16 items corresponding to 9 depression domains are summed to give a single score ranging from 0 to 27, with higher scores denoting greater symptom severity. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	101 ^[49]	98 ^[50]	102 ^[51]	99 ^[52]
Units: units on a scale				
least squares mean (standard error)	-0.9 (± 0.36)	-1.6 (± 0.33)	-0.8 (± 0.32)	-0.7 (± 0.32)

Notes:

[49] - All randomized participants who had baseline and post baseline QIDS-SR16 data.

[50] - All randomized participants who had baseline and post baseline QIDS-SR16 data.

[51] - All randomized participants who had baseline and post baseline QIDS-SR16 data.

[52] - All randomized participants who had baseline and post baseline QIDS-SR16 data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score (28 diarthrodial joint count) Based on C-ReactiveProtein (DAS28-CRP) Measure: Non-Arthritic Disease

End point title	Change From Baseline in Disease Activity Score (28 diarthrodial joint count) Based on C-ReactiveProtein (DAS28-CRP) Measure: Non-Arthritic Disease
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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, baseline cDMARD experience, visit, and treatment-by-visit.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Ixe Q2W	Placebo	ADA Q2W	Ixe Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99 ^[53]	104 ^[54]	99 ^[55]	106 ^[56]
Units: units on a scale				
least squares mean (standard error)	-2.036 (± 0.1225)	-0.835 (± 0.1307)	-1.743 (± 0.1215)	-1.955 (± 0.1206)

Notes:

[53] - All randomized participants who had baseline and post baseline DAS28-CRP data.

[54] - All randomized participants who had baseline and post baseline DAS28-CRP data.

[55] - All randomized participants who had baseline and post baseline DAS28-CRP data.

[56] - All randomized participants who had baseline and post baseline DAS28-CRP data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting the Psoriatic Arthritis Response Criteria (PsARC modified)

End point title	Percentage of Participants Meeting the Psoriatic Arthritis Response Criteria (PsARC modified)
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End point description:

The PsARC is a composite criteria reported in terms of the percentage of participants achieving response

according to the following criterion: TJC, SJC, PGA, and PatGA. Overall response is defined by improvement from baseline assessment in 2 of 4 criteria, 1 of which must be a joint count; there must not be worsening in any of the 4 criteria: at least 30% reduction in TJC, at least 30% reduction in SJC, at least a 20 millimeter (mm) reduction in PGA and at least a 20 mm reduction in PatGA which is equivalent to 20 mm reduction. The results from the 2 VAS measures were assessed as a difference from baseline in mm.

End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[57]	101 ^[58]	107 ^[59]	103 ^[60]
Units: percentage of participants				
number (not applicable)	32	59	58	66

Notes:

[57] - All randomized participants. NRI is applied for IR and participants who had missing data.

[58] - All randomized participants. NRI is applied for IR and participants who had missing data.

[59] - All randomized participants. NRI is applied for IR and participants who had missing data.

[60] - All randomized participants. NRI is applied for IR and participants who had missing data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving Static Physician Global Assessment (sPGA) of 0 or 1 and With at Least a 2-point Improvement From Baseline

End point title	Percentage of Participants achieving Static Physician Global Assessment (sPGA) of 0 or 1 and With at Least a 2-point Improvement From Baseline
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End point description:

The sPGA is the physician's determination of the severity of the participant's psoriasis lesions overall at a given time point. Overall lesions were categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's psoriasis was assessed at a given time point on in which 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe.

End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41 ^[61]	37 ^[62]	52 ^[63]	41 ^[64]
Units: percentage of participants				
number (not applicable)	17	62	65	73

Notes:

[61] - All randomized participants who have plaque psoriasis and sPGA ≥ 3 at baseline. NRI is applied.

[62] - All randomized participants who have plaque psoriasis and sPGA ≥ 3 at baseline. NRI is applied.

[63] - All randomized participants who have plaque psoriasis and sPGA ≥ 3 at baseline. NRI is applied.

[64] - All randomized participants who have plaque psoriasis and sPGA ≥ 3 at baseline. NRI is applied.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in Body Surface Area (BSA)

End point title	Percent change from Baseline in Body Surface Area (BSA)
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End point description:

The investigator evaluated the percentage involvement of psoriasis on each participant's BSA on a continuous scale from 0% = no involvement to 100% = full involvement, where 1% corresponded to the size of the participant's handprint including the palm, fingers, and thumb. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	ADA Q2W	Ixe Q4W	ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99 ^[65]	94 ^[66]	100 ^[67]	91 ^[68]
Units: percent change in BSA				
least squares mean (standard error)	-2.7 (\pm 1.36)	-9.5 (\pm 1.35)	-12.0 (\pm 1.32)	-10.6 (\pm 1.39)

Notes:

[65] - All randomized participants who have plaque psoriasis.

[66] - All randomized participants who have plaque psoriasis.

[67] - All randomized participants who have plaque psoriasis.

[68] - All randomized participants who have plaque psoriasis.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the Nail Psoriasis Severity Index (NAPSI) Score Fingernail Involvement at Baseline

End point title	Change from baseline in the Nail Psoriasis Severity Index (NAPSI) Score Fingernail Involvement at Baseline
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End point description:

The NAPSI scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix Ps by area of involvement. The fingernail is divided into quadrants. Each fingernail is given a score for fingernail bed Ps 0 (none) to 4 (Ps in 4 quadrants of the fingernail) and fingernail matrix Ps 0 (none) to 4 (Ps in 4 quadrants of the matrix), depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed or matrix Ps in each quadrant. The sum of all fingernails equals the total NAPSI score range is from 0 (no effect) to 80 (more severe psoriasis). LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	ADA Q2W	Placebo	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	68 ^[69]	69 ^[70]	66 ^[71]	69 ^[72]
Units: units on a scale				
least squares mean (standard error)	-10.7 (± 1.49)	-2.4 (± 1.66)	-14.0 (± 1.54)	-15.5 (± 1.49)

Notes:

[69] - All randomized participants who had baseline fingernail involvement.

[70] - All randomized participants who had baseline fingernail involvement.

[71] - All randomized participants who had baseline fingernail involvement.

[72] - All randomized participants who had baseline fingernail involvement.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Leeds Dactylitis Index-Basic (LDI-B)

End point title	Change from baseline in Leeds Dactylitis Index-Basic (LDI-B)
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End point description:

The LDI-B measures the severity of dactylitis. In each digit, the ratio of the circumference of the affected digit to the circumference of the digit on the opposite hand or foot measured in mm. Each dactylitic digit was defined by a minimum increase of 10% in circumference over the contra-lateral digit. If the same digits on each hand or foot were thought to be involved, the clinician referred to a table of normative values for a value which was used to provide the comparison. The calculated ratio was multiplied by a tenderness score of 0 (not tender) or 1 (tender). Tenderness was assessed in the area between the joints. The results of each digit were then added to produce a total score. LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Ixe Q2W	Placebo	ADA Q2W	Ixe Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41 ^[73]	39 ^[74]	23 ^[75]	54 ^[76]
Units: units on a scale				
least squares mean (standard error)	-48.3 (± 6.31)	-25.4 (± 6.53)	-57.1 (± 7.84)	-57.1 (± 5.67)

Notes:

[73] - All randomized participants who had baseline and post baseline LDI-score.

[74] - All randomized participants who had baseline and post baseline LDI-score.

[75] - All randomized participants who had baseline and post baseline LDI-score.

[76] - All randomized participants who had baseline and post baseline LDI-score.

Statistical analyses

No statistical analyses for this end point

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

End point title	Change from Baseline in in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
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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, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75 ^[77]	73 ^[78]	85 ^[79]	71 ^[80]
Units: units on a scale				
least squares mean (standard error)	-1.25 (± 0.268)	-2.42 (± 0.249)	-2.74 (± 0.234)	-2.91 (± 0.251)

Notes:

[77] - All randomized participants who had baseline axial involvement defined as baseline BASDAI score >4.

[78] - All randomized participants who had baseline axial involvement defined as baseline BASDAI score >4.

[79] - All randomized participants who had baseline axial involvement defined as baseline BASDAI score >4.

[80] - All randomized participants who had baseline axial involvement defined as baseline BASDAI score >4.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment Emergent Anti-Ixekizumab Antibodies (TE-ADA) and Neutralizing Antibodies (NAb)

End point title	Number of Participants with Treatment Emergent Anti-Ixekizumab Antibodies (TE-ADA) and Neutralizing Antibodies (NAb)
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End point description:

Number of participants with positive treatment emergent anti-ixekizumab antibodies and NAb was summarized by treatment group.

End point type	Secondary
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End point timeframe:

Baseline to Week 24

End point values	Ixe Q4W	Placebo	Ixe Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	107 ^[81]	103 ^[82]	100 ^[83]	
Units: participants				
number (not applicable)				
Treatment Emergent (TE)	6	0	5	
NAb	0	0	0	

Notes:

[81] - All randomized participants received at least 1 dose of ixekizumab and had evaluable antibody measurement.

[82] - All randomized participants received at least 1 dose of ixekizumab and had evaluable antibody measurement.

[83] - All randomized participants received at least 1 dose of ixekizumab and had evaluable antibody measurement.

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology-N (ACR-N) Score

End point title	American College of Rheumatology-N (ACR-N) Score
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End point description:

The ACR-N is defined as each participant's lowest percent improvement from Baseline to Week 24 of 3 measures: tender joint count (68 joints), swollen joint count (66 joints), and the median of the percent change in the remaining 5 ACR core components (physician global assessment, patient global assessment, pain, HAQ, and C-reactive protein). A positive score indicated an improvement from baseline to Week 24. The higher the ACR-N score the better ranging up to 100%. LS mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, 24 Weeks

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[84]	101 ^[85]	107 ^[86]	103 ^[87]
Units: units on a scale				
least squares mean (standard error)	-4.182 (± 6.1417)	28.517 (± 5.9189)	33.509 (± 5.8905)	30.391 (± 5.9736)

Notes:

[84] - All randomized participants with post-baseline ACR data.

[85] - All randomized participants with post-baseline ACR data.

[86] - All randomized participants with post-baseline ACR data.

[87] - All randomized participants with post-baseline ACR data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in TJC

End point title	Change from Baseline in TJC
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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 Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	Ixe Q4W	ADA Q2W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[88]	107 ^[89]	100 ^[90]	102 ^[91]
Units: units on a scale				
least squares mean (standard error)	-4.7 (± 1.14)	-11.9 (± 1.08)	-10.1 (± 1.10)	-13.6 (± 1.09)

Notes:

[88] - All randomized participants with baseline and post-baseline TJC data.

[89] - All randomized participants with baseline and post-baseline TJC data.

[90] - All randomized participants with baseline and post-baseline TJC data.

[91] - All randomized participants with baseline and post-baseline TJC data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SJC

End point title	Change from Baseline in SJC
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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 Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	Ixe Q4W	ADA Q2W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[92]	107 ^[93]	100 ^[94]	102 ^[95]
Units: units on a scale				
least squares mean (standard error)	-3.5 (± 0.62)	-7.0 (± 0.59)	-6.1 (± 0.59)	-8.3 (± 0.59)

Notes:

[92] - All randomized participants with baseline and post-baseline SJC data.

[93] - All randomized participants with baseline and post-baseline SJC data.

[94] - All randomized participants with baseline and post-baseline SJC data.

[95] - All randomized participants with baseline and post-baseline SJC data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Patient's Assessment of Pain VAS

End point title	Change from Baseline in Patient's Assessment of Pain VAS
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End point description:

The VAS is an instrument used to measure a person's subjective quantitative evaluation of an item such as pain intensity. The VAS contains a continuous line between two end points whereby the respondent places a mark on the line to indicate his or her response. In this study, participants scored their pain intensity in the most affected joint of the gout flare on a 0 100 mm VAS. The scale ranged from 0 (no pain) to 100 (unbearable pain). The scores were measured to the nearest millimeter from the left. LS mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	Ixe Q2W	ADA Q2W	Ixe Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	105 ^[96]	98 ^[97]	99 ^[98]	104 ^[99]
Units: units on a scale				
least squares mean (standard error)	-14.0 (± 2.68)	-31.6 (± 2.54)	-30.0 (± 2.52)	-29.6 (± 2.51)

Notes:

[96] - All randomized participants with baseline and post-baseline patient's assessment of pain data.

[97] - All randomized participants with baseline and post-baseline patient's assessment of pain data.

[98] - All randomized participants with baseline and post-baseline patient's assessment of pain data.

[99] - All randomized participants with baseline and post-baseline patient's assessment of pain data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PatGA

End point title	Change from Baseline in PatGA
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End point description:

The Patient's Global Assessment of Disease Severity is a single-item patient reported outcome measure on which participants are asked to rate by circling a number on a 0 to 5 NRS the severity of their psoriasis "today" from 0 (Clear) = no psoriasis to 5 (Severe) = the worst their psoriasis has ever been. LS mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, Week 24

End point values	Placebo	Ixe Q2W	ADA Q2W	Ixe Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	105 ^[100]	98 ^[101]	99 ^[102]	104 ^[103]
Units: units on a scale				
least squares mean (standard error)	-14.8 (± 2.65)	-35.6 (± 2.50)	-31.6 (± 2.49)	-33.8 (± 2.48)

Notes:

[100] - All randomized participants with baseline and post-baseline PaTGA.

[101] - All randomized participants with baseline and post-baseline PaTGA.

[102] - All randomized participants with baseline and post-baseline PaTGA.

[103] - All randomized participants with baseline and post-baseline PaTGA.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physician's Global Assessment of Disease Activity VAS

End point title	Change from Baseline in Physician's Global Assessment of Disease Activity VAS
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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. Least Square (LS) mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.

End point type	Secondary
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End point timeframe:

Baseline, 24 Weeks

End point values	Ixe Q2W	Placebo	ADA Q2W	Ixe Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	95 ^[104]	100 ^[105]	88 ^[106]	96 ^[107]
Units: units on a scale				
least squares mean (standard error)	-42.0 (± 1.99)	-24.2 (± 2.14)	-34.7 (± 2.10)	-38.5 (± 2.06)

Notes:

[104] - All randomized participants with physician's global assessment of disease activity data.

[105] - All randomized participants with physician's global assessment of disease activity data.

[106] - All randomized participants with physician's global assessment of disease activity data.

[107] - All randomized participants with physician's global assessment of disease activity data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CRP

End point title	Change from Baseline in CRP
End point description: CRP was measured with a high sensitivity assay at a central laboratory to assess acute phase reactant. LS mean was calculated using Mixed Model Repeated Measurements (MMRM) analysis with treatment, baseline, geographic region, baseline conventional disease modifying anti-rheumatic drugs (cDMARD) experience, visit, and treatment-by-visit interaction.	
End point type	Secondary
End point timeframe: Baseline, Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106 ^[108]	101 ^[109]	107 ^[110]	103 ^[111]
Units: units on a scale				
least squares mean (standard error)	-3.873 (\pm 1.4292)	-7.512 (\pm 1.2674)	-8.804 (\pm 1.2602)	-8.942 (\pm 1.2552)

Notes:

[108] - All randomized participants with baseline and post-baseline CRP data.

[109] - All randomized participants with baseline and post-baseline CRP data.

[110] - All randomized participants with baseline and post-baseline CRP data.

[111] - All randomized participants with baseline and post-baseline CRP data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Leeds Enthesitis Index (LEI)

End point title	Change from baseline in 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). LS mean was calculated using MMRM analysis with treatment, baseline score, geographic region, baseline cDMARD experience, visit, treatment by visit interaction.	
End point type	Secondary
End point timeframe: Baseline, Week 24	

End point values	Ixe Q2W	Placebo	Ixe Q4W	ADA Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	59 ^[112]	57 ^[113]	70 ^[114]	56 ^[115]
Units: units on a scale				
least squares mean (standard error)	-1.4 (\pm 0.24)	-0.8 (\pm 0.26)	-1.3 (\pm 0.21)	-0.9 (\pm 0.23)

Notes:

[112] - All randomized participants who had baseline and post baseline LEI score.

[113] - All randomized participants who had baseline and post baseline LEI score.

[114] - All randomized participants who had baseline and post baseline LEI score.

[115] - All randomized participants who had baseline and post baseline LEI score.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Psoriasis Area and Severity Index 75%, 90%, 100% (PASI 75, 90, 100)

End point title	Percentage of Participants Achieving Psoriasis Area and Severity Index 75%, 90%, 100% (PASI 75, 90, 100)
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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. Participants achieving PASI 90 were defined as having an improvement of $\geq 90\%$ in the PASI score compared to baseline. Participants achieving PASI 100 were defined as having an improvement of 100% in the PASI score compared to baseline.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38 ^[116]	61 ^[117]	60 ^[118]	49 ^[119]
Units: percentage of participants				
number (not applicable)				
PASI 75	11	55	71	80
PASI 90	6	37	56	68
PASI 100	3	24	43	54

Notes:

[116] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[117] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[118] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

[119] - All randomized participants with baseline psoriatic lesion(s) involving $\geq 3\%$ BSA. NRI is applied.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in itching severity using the Itch NRS

End point title	Change from baseline in itching severity using the Itch NRS
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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 participant's 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, baseline cDMARD experience, visit, and treatment-by-visit interaction.

End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	Placebo	ADA Q2W	Ixe Q4W	Ixe Q2W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67 ^[120]	68 ^[121]	73 ^[122]	59 ^[123]
Units: units on a scale				
least squares mean (standard error)	-0.3 (± 0.32)	-1.7 (± 0.29)	-2.9 (± 0.29)	-2.8 (± 0.31)

Notes:

[120] - All randomized participants who had psoriatic lesion(s) involving $\geq 3\%$ BSA and itch NRS score.

[121] - All randomized participants who had psoriatic lesion(s) involving $\geq 3\%$ BSA and itch NRS score.

[122] - All randomized participants who had psoriatic lesion(s) involving $\geq 3\%$ BSA and itch NRS score.

[123] - All randomized participants who had psoriatic lesion(s) involving $\geq 3\%$ BSA and itch NRS score.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I1F-MC-RHAP

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Placebo (PBO) Double-Blind Period
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Reporting group description:

Participants received placebo for ixekizumab (ixe) as 2 subcutaneous (SC) injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections every 2 weeks (Q2W) from Week 2 to Week 24.

Reporting group title	ADA Double-Blind Period
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Reporting group description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Reporting group title	Ixe Q2W Double-Blind Period
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Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Reporting group title	Ixe Q4W Double-Blind Period
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Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Reporting group title	IR PBO Washout
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Reporting group description:

Participants received placebo for ixekizumab as 2 SC injections and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Placebo for ixekizumab and placebo for adalimumab were given as single SC injections Q2W from Week 2 to Week 24.

Reporting group title	IR Ixe Q4W
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Reporting group description:

Participants received 40 mg of adalimumab as one SC injection and placebo for ixekizumab as 2 SC injections for a total of 3 injections at Week 0. Participants received one SC injection of 40 mg of adalimumab and one SC injection of placebo for ixekizumab Q2W from Week 2 to Week 24.

Reporting group title	IR Ixe Q2W
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Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab or placebo for ixekizumab Q2W from Week 2 to Week 24. Participants received one SC injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Reporting group title	PBO Washout
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Reporting group description:

Participants received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 0. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 2 to Week 24. Participants received one SC

injection of placebo for adalimumab Q2W from Week 2 to Week 24.

Reporting group title	Ixe Q4W
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Reporting group description:

Ixekizumab every 4 weeks (IxeQ4W) and IR IxeQ4W participants received one SC injection of 80 mg of alternating ixekizumab or placebo for ixekizumab Q2W from Week 24 to Week 156.

Placebo and IR placebo (PBO) Washout participants re-randomized to Ixekizumab 80 mg Q4W received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 24. Participants received one SC injection of 80 mg of alternating placebo for ixekizumab or ixekizumab Q2W from Week 26 to Week 156.

PBO Washout participants re-randomized to ixekizumab 80 mg Q4W received one SC injection of 80 mg of alternating ixekizumab or placebo for ixekizumab Q2W from Week 32 to Week 156.

Reporting group title	Ixe Q2W
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Reporting group description:

Ixekizumab Q2W (IxeQ2W) and IR IxeQ2W participants received one SC injection of 80 mg of ixekizumab Q2W from Week 24 to Week 156.

Placebo and IR PBO Washout participants re-randomized to Ixekizumab 80 mg Q2W received a starting dose of 160 mg of ixekizumab given as 2 SC injections of 80 mg and placebo for adalimumab as one SC injection for a total of 3 injections at Week 24. Participants received one SC injection of 80 mg of ixekizumab Q2W from Week 26 to Week 156.

PBO Washout participants re-randomized to ixekizumab 80 mg Q2W received one SC injection of 80 mg of ixekizumab Q2W from Week 32 to Week 156.

Reporting group title	PBO Post-Treatment Follow-up Period
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Reporting group description:

Participants discontinued the study early and entered the post-treatment follow-up period. Participants received placebo immediately prior to entering the post-treatment follow-up period.

Reporting group title	ADA Post-Treatment Follow-up Period
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Reporting group description:

Participants discontinued the study early and entered the post-treatment follow-up period. Participants received adalimumab Q2W immediately prior to entering the post-treatment follow-up period.

Reporting group title	Ixe Q4W Post-Treatment Follow-up Period
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Reporting group description:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q4W immediately prior to entering the post-treatment follow-up period.

Reporting group title	Ixe Q2W Post-treatment Follow-up Period
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Reporting group description:

Participants either completed the study or discontinued the study early and entered the post-treatment follow-up period. Participants received ixekizumab 80 mg Q2W immediately prior to entering the post-treatment follow-up period.

Serious adverse events	Placebo (PBO) Double-Blind Period	ADA Double-Blind Period	Ixe Q2W Double- Blind Period
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 106 (1.89%)	5 / 101 (4.95%)	6 / 107 (5.61%)
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)			
acoustic neuroma			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine benign neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melanocytic naevus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parathyroid tumour benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed ^[1]	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 45 (0.00%)
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			
hypertension			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
hip arthroplasty			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
acquired phimosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[2]	1 / 58 (1.72%)	0 / 50 (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
metrorrhagia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[3]	0 / 58 (0.00%)	1 / 50 (2.00%)	0 / 62 (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

uterine polyp			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[4]	0 / 58 (0.00%)	0 / 50 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[5]	0 / 58 (0.00%)	0 / 50 (0.00%)	0 / 62 (0.00%)
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			
confusional state			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	1 / 106 (0.94%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
anastomotic stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirenal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	1 / 101 (0.99%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery stenosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical myelopathy alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depressed level of consciousness alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
guillain-barre syndrome alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post-traumatic headache alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sciatica			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	1 / 101 (0.99%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal inflammation alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
impaired gastric emptying alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
irritable bowel syndrome alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	1 / 101 (0.99%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
cholecystitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
arthritis bacterial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	1 / 101 (0.99%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis clostridial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 mycoplasmal			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	1 / 101 (0.99%)	0 / 107 (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

upper respiratory tract infection alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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			
obesity alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	0 / 101 (0.00%)	0 / 107 (0.00%)
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 Q4W Double- Blind Period	IR PBO Washout	IR Ixe Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 102 (2.94%)	0 / 9 (0.00%)	0 / 24 (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)			
acoustic neuroma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive ductal breast carcinoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine benign neoplasm			

alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melanocytic naevus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parathyroid tumour benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[1]	0 / 47 (0.00%)	0 / 1 (0.00%)	0 / 8 (0.00%)
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			
hypertension			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
hip arthroplasty			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acquired phimosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 102 (0.98%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[2]	0 / 55 (0.00%)	0 / 8 (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
metrorrhagia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[3]	0 / 55 (0.00%)	0 / 8 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine polyp			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[4]	0 / 55 (0.00%)	0 / 8 (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
vulval disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[5]	0 / 55 (0.00%)	0 / 8 (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			
confusional state			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
anastomotic stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirenal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

post procedural haematoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac disorder alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery occlusion alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery occlusion alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery stenosis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical myelopathy alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 102 (0.98%)	0 / 9 (0.00%)	0 / 24 (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
depressed level of consciousness alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
guillain-barre syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post-traumatic headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal inflammation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
impaired gastric emptying			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 102 (0.98%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
irritable bowel syndrome alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophagitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders cholecystitis acute alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
arthritis bacterial			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis clostridial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 102 (0.98%)	0 / 9 (0.00%)	0 / 24 (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

latent tuberculosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal candidiasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 102 (0.98%)	0 / 9 (0.00%)	0 / 24 (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 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
obesity			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 102 (0.00%)	0 / 9 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IR Ixe Q2W	PBO Washout	Ixe Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	1 / 88 (1.14%)	28 / 187 (14.97%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acoustic neuroma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine benign neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melanocytic naevus			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parathyroid tumour benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[1]	0 / 8 (0.00%)	0 / 50 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	1 / 88 (1.14%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
hip arthroplasty			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acquired phimosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[2]	0 / 16 (0.00%)	0 / 38 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metrorrhagia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[3]	0 / 16 (0.00%)	0 / 38 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine polyp			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[4]	0 / 16 (0.00%)	0 / 38 (0.00%)	0 / 109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[5]	0 / 16 (0.00%)	0 / 38 (0.00%)	1 / 109 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
anastomotic stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirenal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tendon rupture alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 1 0 / 0
Cardiac disorders acute myocardial infarction alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 1 0 / 0
atrial fibrillation alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
cardiac disorder alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 2 0 / 0
coronary artery disease alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
coronary artery occlusion alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 1 0 / 0
myocardial ischaemia alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
cervical myelopathy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depressed level of consciousness			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
guillain-barre syndrome			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post-traumatic headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sciatica			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal inflammation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
impaired gastric emptying			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
irritable bowel syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

oesophagitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	2 / 187 (1.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

intervertebral disc protrusion alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
lumbar spinal stenosis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
osteoarthritis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 1 0 / 0
psoriatic arthropathy alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
Infections and infestations arthritis bacterial alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 1 / 1 0 / 0
cellulitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
chronic tonsillitis alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis clostridial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
latent tuberculosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 24 (0.00%)	0 / 88 (0.00%)	1 / 187 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

oesophageal candidiasis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
pneumonia alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	2 / 187 (1.07%) 1 / 2 0 / 0
pneumonia mycoplasmal alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	0 / 187 (0.00%) 0 / 0 0 / 0
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 1 / 1 0 / 0
Metabolism and nutrition disorders obesity alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 24 (0.00%) 0 / 0 0 / 0	0 / 88 (0.00%) 0 / 0 0 / 0	1 / 187 (0.53%) 0 / 2 0 / 0

Serious adverse events	Ixe Q2W	PBO Post-Treatment Follow-up Period	ADA Post-Treatment Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 183 (10.38%)	0 / 20 (0.00%)	0 / 1 (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) acoustic neuroma			

alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
large intestine benign neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melanocytic naevus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parathyroid tumour benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
prostate cancer			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed ^[1]	0 / 92 (0.00%)	0 / 10 (0.00%)	0 / 1 (0.00%)
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			
hypertension			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
hip arthroplasty			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
acquired phimosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bartholin's cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[2]	0 / 91 (0.00%)	0 / 10 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metrorrhagia			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed ^[3]	0 / 91 (0.00%)	0 / 10 (0.00%)	0 / 1 (0.00%)
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 polyp			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[4]	0 / 91 (0.00%)	0 / 10 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[5]	0 / 91 (0.00%)	0 / 10 (0.00%)	0 / 1 (0.00%)
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			
confusional state			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
anastomotic stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
fibula fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
limb injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lumbar vertebral fracture alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
perirenal haematoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural haematoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
tendon rupture alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac disorder alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 183 (1.09%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery occlusion alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery occlusion alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carotid artery stenosis alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical myelopathy alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depressed level of consciousness alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
guillain-barre syndrome alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
ischaemic stroke alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post-traumatic headache alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sciatica			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 inflammation alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
impaired gastric emptying alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
irritable bowel syndrome alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
oesophagitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
cholecystitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriatic arthropathy			

alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
arthritis bacterial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 183 (0.55%)	0 / 20 (0.00%)	0 / 1 (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
gastroenteritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis clostridial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 mycoplasmal			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

upper respiratory tract infection alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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			
obesity alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 183 (0.00%)	0 / 20 (0.00%)	0 / 1 (0.00%)
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 Q4W Post- Treatment Follow-up Period	Ixe Q2W Post- treatment Follow-up Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 165 (1.21%)	2 / 171 (1.17%)	
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)			
acoustic neuroma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cancer alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive ductal breast carcinoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine benign neoplasm			

alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
melanocytic naevus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
parathyroid tumour benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed ^[1]	0 / 71 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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			
hip arthroplasty			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 165 (0.61%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
acquired phimosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bartholin's cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[2]	0 / 94 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metrorrhagia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[3]	0 / 94 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine polyp			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[4]	0 / 94 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vulval disorder			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed ^[5]	0 / 94 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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			
anastomotic stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibula fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
humerus fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint dislocation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ligament injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
limb injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar vertebral fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
perirenal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

post procedural haematoma alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 myocardial infarction alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac disorder alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery disease alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery occlusion alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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			
carotid artery occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid artery stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical myelopathy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depressed level of consciousness			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
guillain-barre syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic stroke			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
post-traumatic headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatica			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal inflammation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
impaired gastric emptying			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
irritable bowel syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	1 / 171 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholelithiasis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar spinal stenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0			
subjects affected / exposed	1 / 165 (0.61%)	0 / 171 (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			
arthritis bacterial			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis clostridial			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
herpes zoster			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia mycoplasmal alternative dictionary used: MedDRA 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders obesity alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (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 event is gender specific, only occurring in male and female subjects. The number of subjects exposed is 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 event is gender specific, only occurring in male and female subjects. The number of subjects exposed is 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 event is gender specific, only occurring in male and female subjects. The number of subjects exposed is 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 event is gender specific, only occurring in male and female subjects. The number of subjects exposed is adjusted accordingly.

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

Justification: The event is gender specific, only occurring in male and female subjects. The number of subjects exposed is adjusted accordingly.

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

Non-serious adverse events	Placebo (PBO) Double-Blind Period	ADA Double-Blind Period	Ixe Q2W Double- Blind Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 106 (15.09%)	18 / 101 (17.82%)	33 / 107 (30.84%)
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	2 / 101 (1.98%)	7 / 107 (6.54%)
occurrences (all)	0	5	11
injection site reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	3 / 101 (2.97%)	13 / 107 (12.15%)
occurrences (all)	0	5	31
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 106 (0.00%)	3 / 101 (2.97%)	2 / 107 (1.87%)
occurrences (all)	0	3	2
Infections and infestations			

bronchitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	3 / 106 (2.83%) 3	4 / 101 (3.96%) 5	3 / 107 (2.80%) 3
pharyngitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 106 (0.94%) 1	0 / 101 (0.00%) 0	1 / 107 (0.93%) 1
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	7 / 106 (6.60%) 7	5 / 101 (4.95%) 5	5 / 107 (4.67%) 5
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	5 / 106 (4.72%) 6	6 / 101 (5.94%) 7	6 / 107 (5.61%) 6

Non-serious adverse events	Ixe Q4W Double-Blind Period	IR PBO Washout	IR Ixe Q4W
Total subjects affected by non-serious adverse events subjects affected / exposed	31 / 102 (30.39%)	0 / 9 (0.00%)	0 / 24 (0.00%)
General disorders and administration site conditions injection site erythema alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	13 / 102 (12.75%) 42	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	16 / 102 (15.69%) 63	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
Infections and infestations			

bronchitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 4	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
pharyngitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 4	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	0 / 9 (0.00%) 0	0 / 24 (0.00%) 0

Non-serious adverse events	IR Ixe Q2W	PBO Washout	Ixe Q4W
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 24 (0.00%)	7 / 88 (7.95%)	62 / 187 (33.16%)
General disorders and administration site conditions injection site erythema alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 88 (0.00%) 0	3 / 187 (1.60%) 6
injection site reaction alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 88 (0.00%) 0	12 / 187 (6.42%) 63
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 88 (0.00%) 0	11 / 187 (5.88%) 11
Infections and infestations			

bronchitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 88 (0.00%) 0	10 / 187 (5.35%) 13
pharyngitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	2 / 88 (2.27%) 2	5 / 187 (2.67%) 7
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	2 / 88 (2.27%) 3	21 / 187 (11.23%) 27
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	3 / 88 (3.41%) 3	21 / 187 (11.23%) 32

Non-serious adverse events	Ixe Q2W	PBO Post-Treatment Follow-up Period	ADA Post-Treatment Follow-up Period
Total subjects affected by non-serious adverse events subjects affected / exposed	66 / 183 (36.07%)	0 / 20 (0.00%)	0 / 1 (0.00%)
General disorders and administration site conditions injection site erythema alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 51	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 180	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	6 / 183 (3.28%) 6	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
Infections and infestations			

bronchitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	10 / 183 (5.46%) 11	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
pharyngitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	12 / 183 (6.56%) 14	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	18 / 183 (9.84%) 23	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	21 / 183 (11.48%) 23	0 / 20 (0.00%) 0	0 / 1 (0.00%) 0

Non-serious adverse events	Ixe Q4W Post-Treatment Follow-up Period	Ixe Q2W Post-treatment Follow-up Period	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 165 (0.00%)	0 / 171 (0.00%)	
General disorders and administration site conditions injection site erythema alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0 0 / 165 (0.00%) 0	0 / 171 (0.00%) 0 0 / 171 (0.00%) 0	
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0	0 / 171 (0.00%) 0	

Infections and infestations bronchitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0	0 / 171 (0.00%) 0	
pharyngitis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0	0 / 171 (0.00%) 0	
upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0	0 / 171 (0.00%) 0	
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 165 (0.00%) 0	0 / 171 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 October 2012	<p>The changes overall made to the protocol were as follows:</p> <ul style="list-style-type: none">-Rescue therapy modified-Participant Level discontinuation criteria applied-Total Study Duration shortened to 3 years-Exclusion Criteria Modified- Added discontinuation for positive HBV DNA test results- Monitoring added to study schedule and preference on the participant's geographic location during self-injection- Appropriate premedication and modification to allowed concomitant therapy- Updated study schedule by deleting visits 25-33

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported