Clinical trial results:
A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Ixekizumab Dosing Regimens in Patients with Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2015-000190-12
Trial protocol	DE HU CZ PL RO
Global end of trial date	03 August 2017

Results information

Result version number	v1 (current)
This version publication date	18 August 2018
First version publication date	18 August 2018

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHBP

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02513550
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15988

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 Eastern time (UTC/GMT - 5 hours, EST), Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, 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	03 August 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of continuous every 2-week (Q2W) dosing versus continuous every 4-week (Q4W) dosing of ixekizumab in the treatment of patients with moderate-to-severe plaque psoriasis (Ps), as measured by static Physician Global Assessment (sPGA) (0,1) and PASI 75 (75% improvement from baseline in the Psoriasis Area and Severity Index).

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 August 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Puerto Rico: 59
Country: Number of subjects enrolled	Argentina: 37
Country: Number of subjects enrolled	Romania: 19
Country: Number of subjects enrolled	Hungary: 44
Country: Number of subjects enrolled	United States: 474
Country: Number of subjects enrolled	Czech Republic: 14
Country: Number of subjects enrolled	Japan: 16
Country: Number of subjects enrolled	Canada: 196
Country: Number of subjects enrolled	Korea, Republic of: 75
Country: Number of subjects enrolled	Taiwan: 20
Country: Number of subjects enrolled	Poland: 169
Country: Number of subjects enrolled	Mexico: 35
Country: Number of subjects enrolled	Australia: 56
Country: Number of subjects enrolled	Germany: 41
Worldwide total number of subjects	1255
EEA total number of subjects	287

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)	1107
From 65 to 84 years	148
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

As pre-specified in the analysis plan for the trial, outcome measures will not be reported for the Maximum Extended Enrollment (ME2) arms/groups but only for the main global study arms/groups.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	80 mg Ixekizumab Q4W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

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

Dosage and administration details:

A starting dose of 160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm title	80 mg Ixekizumab Q4W/Q2W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

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

Dosage and administration details:

A starting dose of 160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm title	80 mg Ixekizumab Q2W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	Experimental

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

Dosage and administration details:

A starting dose of ixekizumab 160 mg (Week 0) given as 2 SC injections followed by ixekizumab 80 mg given as 1 SC injection Q2W until Week 52. Placebo administered SQ, Q2W to maintain blind.

Arm title	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

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

Dosage and administration details:

A starting dose of 160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm title	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

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

Dosage and administration details:

A starting dose of 160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm title	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

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

Dosage and administration details:

A starting dose of ixekizumab 160 mg (Week 0) given as 2 SC injections followed by ixekizumab 80 mg given as 1 SC injection Q2W until Week 52. Placebo administered SQ, Q2W to maintain blind.

Number of subjects in period 1	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W
Started	310	306	609
Received at least one dose of study drug	310	306	609
Completed	274	268	537
Not completed	36	38	72
Adverse event, serious fatal	1	-	2
Consent withdrawn by subject	11	11	24
Physician decision	2	-	4
Adverse event, non-fatal	5	13	17
Site terminated by sponsor	1	1	3
Due to personal business	2	-	1
Met exclusion criteria and was not dosed	-	-	1
Lost to follow-up	9	7	11
Lack of efficacy	4	5	6
Protocol deviation	1	1	3

Number of subjects in period 1	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Started	9	5	16
Received at least one dose of study drug	9	5	16
Completed	9	4	15
Not completed	0	1	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	1	-
Site terminated by sponsor	-	-	-
Due to personal business	-	-	-
Met exclusion criteria and was not dosed	-	-	-
Lost to follow-up	-	-	1
Lack of efficacy	-	-	-
Protocol deviation	-	-	-

Period 2

Period 2 title	Post-Treatment Follow-up Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	80 mg Ixekizumab Q4W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	80 mg Ixekizumab Q4W/Q2W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	80 mg Ixekizumab Q2W

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort

Arm description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W
Started	285	283	559
Completed	254	244	496
Not completed	31	39	63
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	12	20	26
Physician decision	2	-	-
Early terminated but completed follow-up	12	16	20
Adverse event, non-fatal	1	1	4
Labor Reasons	-	-	1
Subject move out of town	-	-	1
Lost to follow-up	4	2	7
Subject did not come for Visit-802	-	-	3

Number of subjects in period 2	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Started	9	4	15
Completed	9	4	15
Not completed	0	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Early terminated but completed follow-up	-	-	-
Adverse event, non-fatal	-	-	-
Labor Reasons	-	-	-
Subject move out of town	-	-	-
Lost to follow-up	-	-	-
Subject did not come for Visit-802	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	80 mg Ixekizumab Q4W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.	

Reporting group values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W
Number of subjects	310	306	609
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous Units: years			
arithmetic mean	47.4	45.9	49.0
standard deviation	± 13.50	± 12.85	± 13.61

Gender categorical Units: Subjects			
Female	111	107	199
Male	199	199	410
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	59	55	111
Not Hispanic or Latino	243	244	487
Unknown or Not Reported	8	7	11
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	11	12	23
Asian	31	32	64
Native Hawaiian or Other Pacific Islander	0	0	4
Black or African American	14	8	22
White	251	253	484
More than one race	3	1	12
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Puerto Rico	14	16	29
Argentina	9	9	19
Romania	5	5	9
Hungary	11	10	23
United States	119	118	237
Czechia	3	3	8
Japan	5	2	9
Canada	49	49	98
South Korea	11	12	22
Taiwan	5	6	9
Poland	43	43	83
Mexico	10	8	17
Australia	14	14	28
Germany	12	11	18

Reporting group values	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Number of subjects	9	5	16
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age Continuous Units: years			
arithmetic mean	40.0	46.0	46.1
standard deviation	± 9.62	± 13.17	± 13.05
Gender categorical Units: Subjects			
Female	2	0	4
Male	7	5	12
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	9	5	16
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	9	5	16
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Puerto Rico	0	0	0
Argentina	0	0	0
Romania	0	0	0
Hungary	0	0	0
United States	0	0	0
Czechia	0	0	0
Japan	0	0	0
Canada	0	0	0
South Korea	9	5	16
Taiwan	0	0	0
Poland	0	0	0
Mexico	0	0	0
Australia	0	0	0
Germany	0	0	0

Reporting group values	Total		
Number of subjects	1255		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		

Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	423		
Male	832		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	225		
Not Hispanic or Latino	1004		
Unknown or Not Reported	26		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	46		
Asian	157		
Native Hawaiian or Other Pacific Islander	4		
Black or African American	44		
White	988		
More than one race	16		
Unknown or Not Reported	0		
Region of Enrollment Units: Subjects			
Puerto Rico	59		
Argentina	37		
Romania	19		
Hungary	44		
United States	474		
Czechia	14		
Japan	16		
Canada	196		
South Korea	75		
Taiwan	20		
Poland	169		
Mexico	35		
Australia	56		
Germany	41		

End points

End points reporting groups

Reporting group title	80 mg Ixekizumab Q4W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q4W/Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.	
Reporting group title	80 mg Ixekizumab Q2W Maximum Extended Enrollment Cohort
Reporting group description:	
160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ	

injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

Subject analysis set title	80 mg Ixekizumab Q4W continuous
Subject analysis set type	Full analysis

Subject analysis set description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Subject analysis set title	80 mg Ixekizumab Q4W/Q2W No Step
Subject analysis set type	Full analysis

Subject analysis set description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W to week 52. Placebo administered SQ, Q2W to maintain blind.

Subject analysis set title	80 mg Ixekizumab Q4W/Q2W Step up
Subject analysis set type	Full analysis

Subject analysis set description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as one SQ injection Q4W with step-up dosing to Q2W as needed (Q4W/Q2W step-up) to week 52. Placebo administered SQ, Q2W to maintain blind.

Subject analysis set title	80 mg Ixekizumab Q2W continuous
Subject analysis set type	Full analysis

Subject analysis set description:

160 mg ixekizumab given as 2 SQ injections at baseline and then 80 mg ixekizumab given as 1 SQ injection Q2W to week 52. Placebo administered SQ, Q2W to maintain blind.

Primary: Percentage of Participants Achieving Static Physician Global Assessment (sPGA) of (0,1)

End point title	Percentage of Participants Achieving Static Physician Global Assessment (sPGA) of (0,1)[1]

End point description:

The sPGA is the physician's determination of the participant's Psoriasis (Ps) lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's Ps was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. All randomized participants analyzed according to the treatment to which they were assigned. Participants who did not meet the clinical response criteria or had missing data at Week 52 were considered non-responders for Non-Responder Imputation (NRI) analysis.

End point type	Primary

End point timeframe:

Week 52

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	70.6	72.5	78.6	

Statistical analyses

Statistical analysis title	(sPGA) of (0,1)
Comparison groups	80 mg Ixekizumab Q4W v 80 mg Ixekizumab Q2W
Number of subjects included in analysis	919
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	13.9

Statistical analysis title	(sPGA) of (0,1)
Comparison groups	80 mg Ixekizumab Q4W v 80 mg Ixekizumab Q4W/Q2W
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.522
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	9

Primary: Percentage of Participants Achieving 75% Improvement in Psoriasis Area and Severity Index (PASI 75)

End point title	Percentage of Participants Achieving 75% Improvement in Psoriasis Area and Severity Index (PASI 75)[2]

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no Ps to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no Ps) to 72 (the most severe disease). All randomized participants analyzed according to the treatment to which they were assigned.

End point type	Primary

End point timeframe:

Week 52

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	79	83.7	85.9	

Statistical analyses

Statistical analysis title	PASI 75
Comparison groups	80 mg Ixekizumab Q4W v 80 mg Ixekizumab Q2W
Number of subjects included in analysis	919
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	12.2

Statistical analysis title	PASI 75
Comparison groups	80 mg Ixekizumab Q4W v 80 mg Ixekizumab Q4W/Q2W
Number of subjects included in analysis	616
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.118
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	10.8

Secondary: Percentage of Participants Achieving sPGA (0)

End point title	Percentage of Participants Achieving sPGA (0)[3]

End point description:

The sPGA is the physician's determination of the participant's Ps lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's Ps was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. All randomized participants analyzed according to the treatment to which they were assigned. Participants who did not meet the clinical response criteria or had missing data at Week 52 were considered non-responders for Non-Responder Imputation (NRI) analysis.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	44.8	48.7	60.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving PASI 90

End point title	Percentage of Participants Achieving PASI 90[4]

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no Ps to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no Ps) to 72 (the most severe disease). All randomized participants analyzed according to the treatment to which they were assigned.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	65.2	73.9	79.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving PASI 100

End point title	Percentage of Participants Achieving PASI 100[5]

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no Ps to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no Ps) to 72 (the most severe disease). All randomized participants analyzed according to the treatment to which they were assigned.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	43.5	49.3	59.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PASI

End point title	Change from Baseline in PASI[6]

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no Ps to 72 for the most severe disease. Least Squares mean

(LSmean) was calculated using Mixed-Effects Model of Repeated Measures (MMRM) analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and had a baseline and post-baseline measurement for PASI.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	274	268	538	
Units: units on a scale				
least squares mean (standard error)	-18.34 (± 0.22)	-18.95 (± 0.22)	-19.41 (± 0.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement in PASI

End point title	Percent Improvement in PASI[7]

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no Ps to 72 for the most severe disease. Least Squares mean (LSmean) was calculated using Mixed-Effects Model of Repeated Measures (MMRM) analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and had a baseline and post-baseline measurement for PASI.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	274	268	538	
Units: Percent change				
least squares mean (standard error)	91.09 (± 0.89)	94.24 (± 0.90)	96.25 (± 0.71)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Percent Body Surface Area (BSA) Involvement

End point title	Mean Change from Baseline in Percent Body Surface Area (BSA) Involvement[8]

End point description:

The percentage involvement of psoriasis on each participant's body surface area (BSA) was assessed by the investigator on a continuous scale from 0% (no involvement) to 100% (full involvement), in which 1% corresponds to the size of the participant's hand including palm, fingers and thumb. LS mean was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned who had baseline and a post-baseline measurement for BSA affected by Psoriasis.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	274	268	538	
Units: Percent Body Surface Affected				
least squares mean (standard error)	-23.93 (± 0.34)	-24.62 (± 0.34)	-25.01 (± 0.27)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Mean Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Score[9]

End point description:

The NAPSI is a numeric, reproducible, objective tool for evaluation of fingernail (fn) Ps. This scale is used to evaluate the severity of fn bed Ps and fn matrix Ps by area of involvement in the fn unit. The fn is divided with imaginary horizontal and longitudinal lines into quadrants. Each fn is given a score for fn bed Ps (0 to 4) and fn matrix Ps (0 to 4) depending on presence (score of 1) or absence (score of 0) of

any of the features of fn bed and fn matrix Ps in each quadrant. The NAPSI score of a fn is sum of scores in fn bed and fn matrix from each quadrant (maximum of 8). Each fn is evaluated, then the sum of all fn equals the total NAPSI score with a range from 0 to 80 (0 indicates no Ps, 80 indicates worst Ps). LS mean was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	156[10]	148	314	
Units: units on a scale				
least squares mean (standard error)	-19.27 (± 0.81)	-19.87 (± 0.83)	-20.82 (± 0.62)	

Notes:

[10] - All randomized participants who had baseline fingernail involvement and a post-baseline measurement.

Statistical analyses

No statistical analyses for this end point

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

End point title	Mean Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Score[11]

End point description:

The PSSI is a physician assessment of erythema, induration and desquamation and percent of scalp that is covered with a scores range from 0 (none) to 4 (very severe). The composite score is derived from the sum of scores for erythema, induration, and desquamation multiplied by the score recorded for the extent of the scalp area involved, 1 (<10%) to 6 (90-100%) with a total score ranging from 0 (less severity) to 72 (more severity). LS mean change was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and had baseline scalp involvement and had a post-baseline measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	252	245	477	
Units: units on a scale				
least squares mean (standard error)	-18.35 (± 0.31)	-18.73 (± 0.31)	-18.65 (± 0.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Palmoplantar PASI (PPASI)

End point title	Mean Change from Baseline in Palmoplantar PASI (PPASI)[12]

End point description:

The Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 (no PPASI) to 72 (most severe PPASI). The PPASI was only assessed if participants have palmoplantar psoriasis at baseline. LS mean was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and had baseline palmoplantar Ps involvement and had post-baseline measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	82	150	
Units: units on a scale				
least squares mean (standard error)	-9.55 (± 0.31)	-9.37 (± 0.30)	-9.00 (± 0.26)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving an Itch Numeric Rating Scale (Itch NRS) ≥4 point Reduction from Baseline

End point title	Percentage of Participants Achieving an Itch Numeric Rating Scale (Itch NRS) ≥4 point Reduction from Baseline[13]

End point description:

The Itch NRS is a participant-administered single-item 11-point horizontal scale anchored at 0 and 10,

with 0 representing “no itch” and 10 representing “worst itch imaginable.” Overall severity of a participant's itching from Ps is indicated by circling the number that best describes the worst level of itching in the past 24 hours. All randomized participants analyzed according to the treatment to which they were assigned and who had baseline Itch NRS score greater than or equal to (>=) 4.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	254	260	505	
Units: Percentage of participants				
number (not applicable)	74.0	72.3	77.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Dermatology Life Quality Index (DLQI) total score of 0 and 1 (DLQI [0,1])

End point title	Percentage of Participants Achieving Dermatology Life Quality Index (DLQI) total score of 0 and 1 (DLQI [0,1])[14]

End point description:

The DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "not at all," "a lot," and "very much," with corresponding scores of 1, 2, and 3, respectively, and unanswered ("not relevant") responses scored as "0." Totals range from 0 to 30 (less to more impairment). All randomized participants analyzed according to the treatment to which they were assigned.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	310	306	609	
Units: Percentage of participants				
number (not applicable)	66.1	70.3	74.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DLQI Total Score

End point title	Change from Baseline in DLQI Total Score[15]

End point description:

The DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "not at all," "a lot," and "very much," with corresponding scores of 1, 2, and 3, respectively, and unanswered ("not relevant") responses scored as "0." Totals range from 0 to 30 (less to more impairment). LS mean change was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and who had baseline and post-baseline DLQI data.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	273	265	538	
Units: units on a scale				
least squares mean (standard error)	-9.70 (± 0.21)	-9.97 (± 0.22)	-10.23 (± 0.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Itch NRS score

End point title	Change from Baseline in Itch NRS score[16]

End point description:

The Itch NRS is a participant-administered single-item 11-point horizontal scale anchored at 0 and 10, with 0 representing “no itch” and 10 representing “worst itch imaginable.” Overall severity of a participant's itching from Ps is indicated by circling the number that best describes the worst level of itching in the past 24 hours. LS mean change from baseline in PSSI was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to

unstructured. All randomized participants analyzed according to the treatment to which they were assigned and who had baseline and post-baseline Itch NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	274	268	537	
Units: units on a scale				
least squares mean (standard error)	-4.90 (± 0.13)	-5.15 (± 0.13)	-5.33 (± 0.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Skin Pain Visual Analog Scale (VAS)

End point title	Change from Baseline in Skin Pain Visual Analog Scale (VAS)[17]

End point description:

The pain VAS is a participant-administered single-item scale designed to measure Skin pain from Psoriasis using a 0-100 millimeter (mm) horizontal VAS. Overall severity of participant's skin pain from Psoriasis is indicated by placing a single mark on the horizontal 100 mm scale from 0 mm (no skin pain) to 100 mm (severe skin pain). LS mean was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and who had baseline and post-baseline skin pain VAS data.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	271	262	532	
Units: mm				
least squares mean (standard error)	-35.50 (± 0.94)	-36.77 (± 0.96)	-38.07 (± 0.74)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in European Quality of Life - 5 Dimensions 5 Level (EQ-5D-5L) VAS

End point title	Change from Baseline in European Quality of Life - 5 Dimensions 5 Level (EQ-5D-5L) VAS[18]

End point description:

EQ-5D-5L is a standardized measure of health status used to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D-5L consists of 2 components: a descriptive system of the respondent's health and a rating of his/her current health state using a 0 (no pain) to 100mm VAS (severe pain). LS mean was calculated using MMRM analysis including dosing regimen, country, baseline weight category, baseline value, visit, dosing regimen-by-visit, and baseline value-by-visit interactions as fixed factors, with variance-covariance structure set to unstructured. All randomized participants analyzed according to the treatment to which they were assigned and who had baseline and post baseline EQ-5D-5L VAS data.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	268	264	519	
Units: mm				
least squares mean (standard error)	11.93 (± 0.94)	12.47 (± 0.95)	14.42 (± 0.74)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Trough Concentration at Steady State (Ctrough,ss) of Ixekizumab

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

End point description:

Trough concentrations at steady state of Ixekizumab were evaluated. All randomized participants analyzed according to treatment to which they were assigned with evaluable PK samples that met the definition of being a trough concentration.

End point type	Secondary

End point timeframe:

Predose, Week 4, 12, 24, 36 and 52 Post dose

End point values	80 mg Ixekizumab Q4W continuous	80 mg Ixekizumab Q4W/Q2W No Step	80 mg Ixekizumab Q4W/Q2W Step up	80 mg Ixekizumab Q2W continuous
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	304	232	73	602
Units: microgram per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Week 4	3.55 (± 76)	4.03 (± 72)	2.78 (± 67)	7.87 (± 63)
Week 12	2.72 (± 72)	2.81 (± 80)	1.95 (± 70)	8.23 (± 56)
Week 24	2.65 (± 73)	2.71 (± 85)	3.48 (± 78)	7.89 (± 66)
Week 36	2.83 (± 74)	2.88 (± 73)	5.76 (± 67)	7.73 (± 76)
Week 52	2.43 (± 79)	2.77 (± 73)	5.73 (± 68)	6.96 (± 87)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Ixekizumab Antibodies

End point title	Number of Participants with Anti-Ixekizumab Antibodies[19]

End point description:

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

End point type	Secondary

End point timeframe:

Baseline through Week 52

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned for this endpoint as per the protocol or Statistical Analysis Plan or both.

End point values	80 mg Ixekizumab Q4W	80 mg Ixekizumab Q4W/Q2W	80 mg Ixekizumab Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	307	305	606	
Units: participants				
number (not applicable)	71	64	84	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All the AEs in the Blinded Treatment Dosing Period and Post-Treatment Period of the Study

Adverse event reporting additional description:

I1F-MC-RHBP

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Ixekizumab 80 mg Q2W Blinded Treatment Period - Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80mg Q4W/Q2W Blinded Treatment Period-Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W Blinded Treatment Period - Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q2W Post-Treatment Period - Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W Post-Treatment Period - Global Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q2W Blinded Treatment Period - ME2 Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W/Q2W Blinded Treatment Period - ME2 Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W Blinded Treatment Period - ME2 Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q2W Post-Treatment Period - ME2 Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - ME2 Cohort
Reporting group description: -	
Reporting group title	Ixekizumab 80 mg Q4W Post-Treatment Period - ME2 Cohort
Reporting group description: -	

Serious adverse events	Ixekizumab 80 mg Q2W Blinded Treatment Period - Global Cohort	Ixekizumab 80mg Q4W/Q2W Blinded Treatment Period-Global Cohort	Ixekizumab 80 mg Q4W Blinded Treatment Period - Global Cohort
Total subjects affected by serious adverse events			

subjects affected / exposed	32 / 609 (5.25%)	16 / 306 (5.23%)	16 / 310 (5.16%)
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)			
adenocarcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma gastric			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma of colon			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
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 metastatic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
dermatofibrosarcoma protuberans			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
invasive breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
neurilemmoma benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
plasma cell myeloma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[1]	0 / 199 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubal rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[2]	0 / 199 (0.00%)	0 / 107 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vascular stent restenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[3]	0 / 410 (0.00%)	0 / 199 (0.00%)	1 / 199 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary microemboli			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
stress			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
suicide attempt			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
international normalised ratio increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
Injury, poisoning and procedural complications			
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
femur fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
hand fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
pelvic fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	2 / 306 (0.65%)	0 / 310 (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
road traffic accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

wound dehiscence			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
atrial fibrillation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
pericarditis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
Nervous system disorders			
basilar migraine			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
Hyposmia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis eosinophilic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intra-abdominal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
oesophageal rupture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (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
umbilical hernia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
cholelithiasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash macular			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
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			
renal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
cartilage hypertrophy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc compression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carbuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	2 / 306 (0.65%)	2 / 310 (0.65%)
occurrences causally related to treatment / all	0 / 1	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
gastroenteritis shigella			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
pneumonia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pyelonephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
Metabolism and nutrition disorders			
diabetic ketoacidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
gout			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	0 / 310 (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
lactic acidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ixekizumab 80 mg Q2W Post-Treatment Period - Global Cohort	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - Global Cohort	Ixekizumab 80 mg Q4W Post-Treatment Period - Global Cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 559 (1.25%)	2 / 283 (0.71%)	1 / 285 (0.35%)
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)			
adenocarcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
adenocarcinoma gastric			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma of colon			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 metastatic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatofibrosarcoma protuberans			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neurilemmoma benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

plasma cell myeloma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[1]	1 / 184 (0.54%)	0 / 98 (0.00%)	0 / 98 (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
tubal rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[2]	1 / 184 (0.54%)	0 / 98 (0.00%)	0 / 98 (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
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 stent restenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[3]	0 / 375 (0.00%)	0 / 185 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary microemboli			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			

alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
international normalised ratio increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used:			

MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
rib fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
road traffic accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
coronary artery disease			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
basilar migraine			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (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
Hyposmia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 eosinophilic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intra-abdominal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
rash macular			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
renal haematoma			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
cartilage hypertrophy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc compression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
carbuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 shigella			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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			
diabetic ketoacidosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gout			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (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
hypokalaemia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lactic acidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
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	Ixekizumab 80 mg Q2W Blinded Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W/Q2W Blinded Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W Blinded Treatment Period - ME2 Cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (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)			
adenocarcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma gastric			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma of colon			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer metastatic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatofibrosarcoma protuberans			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neurilemmoma benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
plasma cell myeloma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubal rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[2]	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

chest discomfort			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 stent restenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[3]	0 / 12 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary microemboli			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

anxiety			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
international normalised ratio increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			

clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
basilar migraine			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyposmia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 eosinophilic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intra-abdominal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash macular			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
renal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
cartilage hypertrophy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc compression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carbuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 shigella			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urosepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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			
diabetic ketoacidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gout			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lactic acidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
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	Ixekizumab 80 mg Q2W Post-Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W Post-Treatment Period - ME2 Cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (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)			

adenocarcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma gastric			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma of colon			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 metastatic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatofibrosarcoma protuberans			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive breast carcinoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neurilemmoma benign			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
plasma cell myeloma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubal rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[2]	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 stent restenosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed[3]	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary microemboli			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
international normalised ratio increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
clavicle fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound dehiscence			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
basilar migraine			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyposmia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
colitis ulcerative			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
crohn's disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 eosinophilic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intra-abdominal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 rupture			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

umbilical hernia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoriasis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rash macular			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
renal haematoma			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
cartilage hypertrophy			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc compression			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abscess oral			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
carbuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic sinusitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 shigella			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
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			
diabetic ketoacidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gout			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lactic acidosis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

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

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

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

Non-serious adverse events	Ixekizumab 80 mg Q2W Blinded Treatment Period - Global Cohort	Ixekizumab 80mg Q4W/Q2W Blinded Treatment Period- Global Cohort	Ixekizumab 80 mg Q4W Blinded Treatment Period - Global Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	285 / 609 (46.80%)	136 / 306 (44.44%)	157 / 310 (50.65%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	3 / 609 (0.49%)	2 / 306 (0.65%)	7 / 310 (2.26%)
occurrences (all)	3	2	7
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	3 / 609 (0.49%)	2 / 306 (0.65%)	5 / 310 (1.61%)
occurrences (all)	3	2	5
blood glucose increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
helicobacter test positive			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

dizziness			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	9 / 609 (1.48%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences (all)	10	0	1
headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	29 / 609 (4.76%)	16 / 306 (5.23%)	14 / 310 (4.52%)
occurrences (all)	34	18	16
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	18 / 609 (2.96%)	3 / 306 (0.98%)	4 / 310 (1.29%)
occurrences (all)	49	4	14
injection site oedema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences (all)	1	0	4
injection site pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	8 / 609 (1.31%)	6 / 306 (1.96%)	4 / 310 (1.29%)
occurrences (all)	26	7	4
injection site pruritus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 609 (0.66%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences (all)	13	0	4
injection site reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	49 / 609 (8.05%)	5 / 306 (1.63%)	18 / 310 (5.81%)
occurrences (all)	256	15	68
injection site swelling			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	7 / 609 (1.15%)	0 / 306 (0.00%)	2 / 310 (0.65%)
occurrences (all)	11	0	11
xerosis			
alternative dictionary used:			

MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	2 / 306 (0.65%)	1 / 310 (0.32%)
occurrences (all)	1	2	1
Blood and lymphatic system disorders			
neutropenia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	0 / 306 (0.00%)	2 / 310 (0.65%)
occurrences (all)	2	0	2
Eye disorders			
retinal vein occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dry mouth			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	2 / 306 (0.65%)	0 / 310 (0.00%)
occurrences (all)	2	2	0
dyspepsia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 609 (0.66%)	1 / 306 (0.33%)	2 / 310 (0.65%)
occurrences (all)	4	1	2
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences (all)	0	0	1
gastritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 609 (0.66%)	1 / 306 (0.33%)	3 / 310 (0.97%)
occurrences (all)	4	1	3
mouth ulceration			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

cough			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	23 / 609 (3.78%)	2 / 306 (0.65%)	11 / 310 (3.55%)
occurrences (all)	25	3	11
dysphonia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	3 / 609 (0.49%)	0 / 306 (0.00%)	1 / 310 (0.32%)
occurrences (all)	3	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	17 / 609 (2.79%)	5 / 306 (1.63%)	6 / 310 (1.94%)
occurrences (all)	17	5	6
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	1 / 306 (0.33%)	2 / 310 (0.65%)
occurrences (all)	2	1	2
dry skin			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 609 (0.16%)	1 / 306 (0.33%)	0 / 310 (0.00%)
occurrences (all)	1	1	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 609 (0.33%)	1 / 306 (0.33%)	2 / 310 (0.65%)
occurrences (all)	2	1	2
eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	11 / 609 (1.81%)	5 / 306 (1.63%)	6 / 310 (1.94%)
occurrences (all)	12	6	8
psoriasis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	3 / 609 (0.49%)	3 / 306 (0.98%)	4 / 310 (1.29%)
occurrences (all)	3	3	4
rash			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 609 (0.66%)	3 / 306 (0.98%)	3 / 310 (0.97%)
occurrences (all)	4	3	3
urticaria			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	6 / 609 (0.99%)	4 / 306 (1.31%)	3 / 310 (0.97%)
occurrences (all)	7	4	3
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	25 / 609 (4.11%)	5 / 306 (1.63%)	7 / 310 (2.26%)
occurrences (all)	29	5	8
myalgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	6 / 609 (0.99%)	0 / 306 (0.00%)	2 / 310 (0.65%)
occurrences (all)	6	0	2
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 609 (0.66%)	2 / 306 (0.65%)	4 / 310 (1.29%)
occurrences (all)	4	2	4
periarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
furuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	5 / 609 (0.82%)	1 / 306 (0.33%)	3 / 310 (0.97%)
occurrences (all)	5	1	3
hordeolum			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	4 / 609 (0.66%)	2 / 306 (0.65%)	4 / 310 (1.29%)
occurrences (all)	4	2	7
influenza			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	5 / 609 (0.82%)	9 / 306 (2.94%)	6 / 310 (1.94%)
occurrences (all)	5	10	6
mumps			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 609 (0.00%)	0 / 306 (0.00%)	0 / 310 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	8 / 609 (1.31%)	3 / 306 (0.98%)	3 / 310 (0.97%)
occurrences (all)	8	4	4
tinea pedis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	8 / 609 (1.31%)	4 / 306 (1.31%)	6 / 310 (1.94%)
occurrences (all)	10	4	6
tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	6 / 609 (0.99%)	2 / 306 (0.65%)	1 / 310 (0.32%)
occurrences (all)	6	2	2
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	69 / 609 (11.33%)	39 / 306 (12.75%)	46 / 310 (14.84%)
occurrences (all)	93	56	60
urinary tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	15 / 609 (2.46%)	4 / 306 (1.31%)	16 / 310 (5.16%)
occurrences (all)	20	4	21
vaginal infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[4]	0 / 199 (0.00%)	1 / 107 (0.93%)	0 / 111 (0.00%)
occurrences (all)	0	1	0

viral upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	73 / 609 (11.99%)	53 / 306 (17.32%)	41 / 310 (13.23%)
occurrences (all)	89	69	49

Non-serious adverse events	Ixekizumab 80 mg Q2W Post-Treatment Period - Global Cohort	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - Global Cohort	Ixekizumab 80 mg Q4W Post-Treatment Period - Global Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 559 (7.16%)	20 / 283 (7.07%)	16 / 285 (5.61%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	0	1	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	0	1	0
blood glucose increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	0	1	0
helicobacter test positive			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
injection site oedema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
neutropenia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
retinal vein occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dry mouth			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

cough			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 559 (0.36%)	1 / 283 (0.35%)	1 / 285 (0.35%)
occurrences (all)	2	1	1
dysphonia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	1	0	0
epistaxis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	1 / 285 (0.35%)
occurrences (all)	1	0	1
psoriasis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	6 / 559 (1.07%)	5 / 283 (1.77%)	3 / 285 (1.05%)
occurrences (all)	7	5	4
rash			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	3 / 559 (0.54%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	5	0	0
urticaria			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	4 / 559 (0.72%)	1 / 283 (0.35%)	2 / 285 (0.70%)
occurrences (all)	4	1	3
myalgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	0	1	0
periarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
furuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	1 / 285 (0.35%)
occurrences (all)	1	0	1
hordeolum			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 559 (0.00%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	2 / 283 (0.71%)	1 / 285 (0.35%)
occurrences (all)	1	2	1
mumps			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 559 (0.00%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	1 / 283 (0.35%)	0 / 285 (0.00%)
occurrences (all)	1	1	0
tinea pedis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 559 (0.18%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	1	0	0
tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 559 (0.36%)	0 / 283 (0.00%)	0 / 285 (0.00%)
occurrences (all)	2	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	3 / 559 (0.54%)	3 / 283 (1.06%)	1 / 285 (0.35%)
occurrences (all)	3	3	1
urinary tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	6 / 559 (1.07%)	2 / 283 (0.71%)	0 / 285 (0.00%)
occurrences (all)	6	2	0
vaginal infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[4]	0 / 184 (0.00%)	0 / 98 (0.00%)	0 / 98 (0.00%)
occurrences (all)	0	0	0

viral upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	9 / 559 (1.61%)	0 / 283 (0.00%)	6 / 285 (2.11%)
occurrences (all)	9	0	7

Non-serious adverse events	Ixekizumab 80 mg Q2W Blinded Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W/Q2W Blinded Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W Blinded Treatment Period - ME2 Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 16 (68.75%)	4 / 5 (80.00%)	6 / 9 (66.67%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
helicobacter test positive			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	24	0	0
injection site oedema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	24	0	0
injection site pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
injection site pruritus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
injection site reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
xerosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
neutropenia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
retinal vein occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
dry mouth			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
dyspepsia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
mouth ulceration			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

cough			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysphonia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
epistaxis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
dry skin			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
psoriasis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
myalgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
periarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
furuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
hordeolum			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
mumps			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
otitis externa			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
tinea pedis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 16 (6.25%)	1 / 5 (20.00%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
urinary tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[4]	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

viral upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	6 / 16 (37.50%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	9	1	1

Non-serious adverse events	Ixekizumab 80 mg Q2W Post-Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W/Q2W Post-Treatment Period - ME2 Cohort	Ixekizumab 80 mg Q4W Post-Treatment Period - ME2 Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 15 (13.33%)	0 / 4 (0.00%)	2 / 9 (22.22%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
helicobacter test positive			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
benign bone neoplasm			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site oedema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
neutropenia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
retinal vein occlusion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
dry mouth			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastric ulcer			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

cough			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
dysphonia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
rash			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
periarthritis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
furuncle			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mumps			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed[4]	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

viral upper respiratory tract infection			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Notes:

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported