Clinical trial results:
Protocol I6T-MC-AMAF
A Phase 2, Multicenter, Randomized, Parallel-arm, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2016-001098-34
Trial protocol	DE PL
Global end of trial date	08 May 2019

Results information

Result version number	v1 (current)
This version publication date	21 May 2020
First version publication date	21 May 2020

Trial information

Trial identification

Sponsor protocol code	I6T-MC-AMAF

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02899988
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16481

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the efficacy of the study drug mirikizumab in participants with moderate to severe plaque psoriasis.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	United States: 82
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Poland: 65
Country: Number of subjects enrolled	Germany: 15
Worldwide total number of subjects	205
EEA total number of subjects	80

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)	183
From 65 to 84 years	22
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

No Text Available

Period 1

Period 1 title	Induction Period (16 Weeks)
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	Induction: Placebo

Arm description:

Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period.

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

Dosage and administration details:

Placebo subcutaneously (SC) every 8 weeks (Q8W).

Arm title	Induction: 30 mg Mirikizumab Q8W

Arm description:

Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

30 mg mirikizumab SC Q8W.

Arm title	Induction:100 mg Mirikizumab Q8W

Arm description:

Induction:Participants received 100 mg mirikizumab SC Q8W during Induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
100 mg mirikizumab SC Q8W.

Arm title	Induction: 300 mg Mirikizumab Q8W

Arm description:
Induction:
Participants received 300 mg mirikizumab SC Q8W during Induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
300 mg mirikizumab SC Q8W.

Number of subjects in period 1	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W
Started	52	51	51
Received at least one dose of study drug	52	51	51
Completed	50	49	51
Not completed	2	2	0
Consent withdrawn by subject	2	1	-
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-

Number of subjects in period 1	Induction: 300 mg Mirikizumab Q8W
Started	51
Received at least one dose of study drug	51
Completed	49
Not completed	2
Consent withdrawn by subject	-
Physician decision	-
Adverse event, non-fatal	2

Period 2

Period 2 title	Maintenance Period (88 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.
Participants who had ≥ Psoriasis Area and Severity Index (PASI) 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

30 mg mirikizumab as needed (PRN).

Arm title	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.
Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100 mg mirikizumab as needed (PRN).

Arm title	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	Experimental

Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg mirikizumab as needed (PRN).

Arm title	Maintenance: Placebo to 300 mg Mirikizumab Q8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg mirikizumab Q8W.

Arm title	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg mirikizumab Q8W.

Arm title	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg mirikizumab Q8W.

Arm title	Maintenance: 300 mg Mirikizumab Q8W

Arm description:

Maintenance:
Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg mirikizumab SC Q8W.

Number of subjects in period 2	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN
Started	15	30	34
Rescue Participants	0 [1]	0 [2]	0 [3]
Roll over to AMAH (NCT03556202)	9 [4]	18 [5]	26 [6]
Completed	13	27	30
Not completed	2	3	4
Consent withdrawn by subject	1	-	3
Adverse event, non-fatal	1	2	1
Lost to follow-up	-	1	-

Number of subjects in period 2	Maintenance: Placebo to 300 mg Mirikizumab Q8W	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W
Started	50	34	21
Rescue Participants	0 [7]	0 [8]	0 [9]
Roll over to AMAH (NCT03556202)	42 [10]	24 [11]	17 [12]
Completed	45	30	19
Not completed	5	4	2
Consent withdrawn by subject	2	2	-
Adverse event, non-fatal	2	2	2
Lost to follow-up	1	-	-

Number of subjects in period 2	Maintenance: 300 mg Mirikizumab Q8W
Started	15
Rescue Participants	0 [13]
Roll over to AMAH (NCT03556202)	0 [14]

Completed	13
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	1
Lost to follow-up	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started to maintenance period.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: It's a milestone independent of the number that started maintenance period.

Period 3

Period 3 title	Follow-Up (16 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.
Participants who had ≥ PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.
Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN

Arm description:

Maintenance:
Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maintenance: Placebo to 300 mg Mirikizumab Q8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W

Arm description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 3[15]	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN
Started	2	2	3
Completed	2	2	3

Number of subjects in period 3[15]	Maintenance: Placebo to 300 mg Mirikizumab Q8W	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W
Started	3	6	2
Completed	3	6	2

Notes:

[15] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants that completed maintenance period continued to follow-up period.

Baseline characteristics

Reporting groups	
Reporting group title	Induction: Placebo
Reporting group description:	
Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period.	
Reporting group title	Induction: 30 mg Mirikizumab Q8W
Reporting group description:	
Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period.	
Reporting group title	Induction:100 mg Mirikizumab Q8W
Reporting group description:	
Induction:Participants received 100 mg mirikizumab SC Q8W during Induction period.	
Reporting group title	Induction: 300 mg Mirikizumab Q8W
Reporting group description:	
Induction: Participants received 300 mg mirikizumab SC Q8W during Induction period.	

Reporting group values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W
Number of subjects	52	51	51
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	46.0	49.2	46.0
standard deviation	± 12.39	± 13.28	± 13.18
Gender categorical Units: Subjects			
Female	10	12	16
Male	42	39	35
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	8	7	4
Not Hispanic or Latino	39	37	42
Unknown or Not Reported	5	7	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	6	7	7
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	3
White	44	43	41
More than one race	1	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Canada	4	7	7

United States	21	20	18
Japan	4	7	5
Poland	19	14	18
Germany	4	3	3

Reporting group values	Induction: 300 mg Mirikizumab Q8W	Total	
Number of subjects	51	205	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	47.5		
standard deviation	± 13.23	-	
Gender categorical Units: Subjects			
Female	15	53	
Male	36	152	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	24	
Not Hispanic or Latino	42	160	
Unknown or Not Reported	4	21	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	6	26	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	8	
White	42	170	
More than one race	0	1	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
Canada	5	23	
United States	23	82	
Japan	4	20	
Poland	14	65	
Germany	5	15	

End points

End points reporting groups

Reporting group title	Induction: Placebo

Reporting group description:

Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period.

Reporting group title	Induction: 30 mg Mirikizumab Q8W

Reporting group description:

Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period.

Reporting group title	Induction:100 mg Mirikizumab Q8W

Reporting group description:

Induction:Participants received 100 mg mirikizumab SC Q8W during Induction period.

Reporting group title	Induction: 300 mg Mirikizumab Q8W

Reporting group description:

Induction:
Participants received 300 mg mirikizumab SC Q8W during Induction period.

Reporting group title	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.
Participants who had ≥ Psoriasis Area and Severity Index (PASI) 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.
Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: Placebo to 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:
Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

Reporting group title	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.
Participants who had ≥ PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.
Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: Placebo to 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.
Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W

Reporting group description:

Maintenance:
Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

Subject analysis set title	Induction: 30 mg Mirikizumab
Subject analysis set type	Per protocol

Subject analysis set description:

Induction: 30 mg Mirikizumab administered SC every 8 weeks (Q8W).

Subject analysis set title	Induction: 100 mg Mirikizumab
Subject analysis set type	Per protocol

Subject analysis set description:

Induction: 100 mg Mirikizumab administered SC Q8W.

Subject analysis set title	Induction: 300 mg Mirikizumab
Subject analysis set type	Per protocol

Subject analysis set description:

Induction: 300 mg Mirikizumab administered SC Q8W.

Subject analysis set title	30 mg mirikizumab Q8W To 30 mg mirikizumab PRN
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Subject analysis set title	100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Subject analysis set title	300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Subject analysis set title	Placebo to 300 mg Mirikizumab Q8W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had received placebo during induction period.

Subject analysis set title	30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Subject analysis set title	100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Subject analysis set title	300 mg mirikizumab SC Q8W To 300 mg mirikizumab SC Q8W
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received 300 mg mirikizumab SC Q8W during Induction period.

Participants had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

Primary: Percentage of Participants with a ≥90% Improvement in Psoriasis Area and Severity Index (PASI 90)

End point title	Percentage of Participants with a ≥90% Improvement in Psoriasis Area and Severity Index (PASI 90)

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 psoriasis (PsO) 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 PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

End point type	Primary

End point timeframe:

Week 16

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	51
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	29.4 (16.9 to 41.9)	58.8 (45.3 to 72.3)	66.7 (53.7 to 79.6)

Statistical analyses

Statistical analysis title	Participants With a ≥90% Improvement in PASI 90

Statistical analysis description:

Participants With a ≥90% Improvement in PASI 90

Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	29.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	16.9
upper limit	41.9

Statistical analysis title	Participants With a ≥90% Improvement in PASI 90
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	58.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.3
upper limit	72.3

Statistical analysis title	Participants With a ≥90% Improvement in PASI 90
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	66.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.7
upper limit	79.6

Secondary: Percentage of Participants with a 100% Improvement in Psoriasis Area and Severity Index (PASI 100)

End point title	Percentage of Participants with a 100% Improvement in Psoriasis Area and Severity Index (PASI 100)

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 PsO 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 PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

End point type	Secondary
End point timeframe: Week 16	

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	51
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	15.7 (5.7 to 25.7)	31.4 (18.6 to 44.1)	31.4 (18.6 to 44.1)

Statistical analyses

Statistical analysis title	Participants with a 100% Improvement in PASI 100
Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	15.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	25.7

Statistical analysis title	Participants with a 100% Improvement in PASI 100
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	31.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	18.6
upper limit	44.1

Statistical analysis title	Participants with a 100% Improvement in PASI 100
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	31.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.6
upper limit	44.1

Secondary: Percentage of Participants with a ≥75% Improvement in Psoriasis Area and Severity Index (PASI 75)

End point title	Percentage of Participants with a ≥75% Improvement in Psoriasis Area and Severity Index (PASI 75)

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 PsO 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 PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Week 16

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	51
Units: percentage of participants				
number (confidence interval 95%)	3.8 (0 to 9.1)	52.9 (39.2 to 66.6)	78.4 (67.1 to 89.7)	74.5 (62.5 to 86.5)

Statistical analyses

Statistical analysis title	Participants With a ≥75% Improvement in PASI 75
Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	22.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.62
upper limit	89.97

Statistical analysis title	Participants With a ≥75% Improvement in PASI 75
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	74.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.1
upper limit	87

Statistical analysis title	Participants With a ≥75% Improvement in PASI 75
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	70.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.6
upper limit	83.7

Secondary: Percentage of Participants with a Static Physician Global Assessment (sPGA) 0 and 0/1

End point title	Percentage of Participants with a Static Physician Global Assessment (sPGA) 0 and 0/1

End point description:

The sPGA is the physician's determination of the participant's PsO lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's PsO was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. Participants who did not meet the clinical response criteria or had missing data at Week 16 were considered non-responders for non-responder Imputation (NRI) analysis.

End point type	Secondary

End point timeframe:

Week 16

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	51
Units: percentage of participants				
number (confidence interval 95%)				
sPGA (0)	0 (0 to 0)	15.7 (5.7 to 25.7)	31.4 (18.6 to 44.1)	31.4 (18.6 to 44.1)
sPGA (0/1)	1.9 (0 to 5.7)	37.3 (24.0 to 50.5)	70.6 (58.1 to 83.1)	68.6 (55.9 to 81.4)

Statistical analyses

Statistical analysis title	Participants With sPGA 0 and 0/1

Statistical analysis description:

sPGA (0)

Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.041
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	15.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	25.7

Notes:
[1] - sPGA (0)

Statistical analysis title	Participants With sPGA 0 and 0/1
Statistical analysis description: sPGA (0)	
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.007
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	31.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.6
upper limit	44.1

Notes:
[2] - sPGA (0)

Statistical analysis title	Participants With sPGA 0 and 0/1
Statistical analysis description: sPGA (0)	
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.008
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	31.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.6
upper limit	44.1

Notes:
[3] - sPGA (0)

Statistical analysis title	Participants With sPGA 0 and 0/1
Statistical analysis description: sPGA (0/1)	
Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	35.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.5
upper limit	49.1

Notes:
[4] - sPGA (0/1)

Statistical analysis title	Participants With sPGA 0 and 0/1
Statistical analysis description: sPGA (0/1)	
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	68.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.6
upper limit	81.7

Notes:
[5] - sPGA (0/1)

Statistical analysis title	Participants With sPGA 0 and 0/1
Statistical analysis description: sPGA (0/1)	
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	66.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.4
upper limit	80

Notes:

[6] - sPGA (0/1)

Secondary: Mean Change from Baseline on the Psoriasis Symptom Scale (PSS)

End point title	Mean Change from Baseline on the Psoriasis Symptom Scale (PSS)

End point description:

The Psoriasis Symptoms Scale is a patient-administered assessment of 4 symptoms (itch,pain,stinging,and burning); 3 signs(redness,scaling, and cracking); and 1 item on the discomfort related to symptoms/signs.The overall severity for each individual symptom/sign from the patient's psoriasis is indicated by selecting the number from a numeric rating scale(NRS) of 0 to 10 that best describes the worst
level of each symptom/sign in the past 24 hours, where 0=no symptom/sign and 10=worst imaginable symptom/sign. Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region [United States/Outside United States(US/OUS)], previous therapy(yes/no), baseline value,visit, and the interaction treatment-by-visit as fixed factors,covariance structure=heterogeneous autoregressive.

Analysis Population Description:All participants who received at least one dose of study drug who had baseline and at least one post-baseline PSS observation.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	44	44
Units: units on a scale				
least squares mean (standard error)	-4.35 (± 2.29)	-31.19 (± 2.34)	-42.33 (± 2.37)	-33.66 (± 2.27)

Statistical analyses

Statistical analysis title	Change from Baseline on PSS

Statistical analysis description:

Change from Baseline on PSS.

Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-26.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.27
upper limit	-20.42
Variability estimate	Standard error of the mean
Dispersion value	3.26

Statistical analysis title	Change from Baseline on PSS
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-37.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.47
upper limit	-31.51
Variability estimate	Standard error of the mean
Dispersion value	3.29

Statistical analysis title	Change from Baseline on PSS.
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-29.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.66
upper limit	-22.97
Variability estimate	Standard error of the mean
Dispersion value	3.22

Secondary: Mean Change (Improvement) from Baseline on the Patient Global Assessment (PGA)

End point title	Mean Change (Improvement) from Baseline on the Patient Global Assessment (PGA)

End point description:

The Patient's Global Assessment of Disease Severity is a single-item participant-reported outcome measure on which participants are asked to rate the severity of their psoriasis "today" from 0 (Clear) = no psoriasis, to 5 (Severe) = the worst their psoriasis has ever been. Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region (US/OUS), previous therapy (yes/no), baseline value, visit, and the interaction treatment-by-visit as fixed factors, covariance structure = unstructured.

Analysis Population Description: All participants who received at least one dose of study drug who had baseline and at least one post-baseline Patient Global Assessment observation.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	48	51	49
Units: units on a scale				
least squares mean (standard error)	0.35 (± 0.16)	2.24 (± 0.16)	2.91 (± 0.16)	2.82 (± 0.16)

Statistical analyses

Statistical analysis title	Mean Change (Improvement) From Baseline on PGA

Statistical analysis description:

Mean Change (Improvement) From Baseline on PGA

Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.45
upper limit	2.34
Variability estimate	Standard error of the mean
Dispersion value	0.22

Statistical analysis title	Mean Change (Improvement) From Baseline on PGA
Comparison groups	Induction:100 mg Mirikizumab Q8W v Induction: Placebo
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.23
upper limit	3
Variability estimate	Standard error of the mean
Dispersion value	0.22

Statistical analysis title	Mean Change (Improvement) From Baseline on PGA
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.03
upper limit	2.91

Variability estimate	Standard error of the mean
Dispersion value	0.22

Secondary: Mean Change from Baseline on the Dermatology Life Quality Index (DLQI) Total Score

End point title	Mean Change from Baseline on the Dermatology Life Quality Index (DLQI) Total Score

End point description:

The DLQI is patient-reported, 10-question, validated, quality-of-life questionnaire that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Questions 3-10 also have an additional response category of "Not relevant" which is scored as "0". For all questions, if unanswered the question is scored as "0". Totals range from 0 to 30 (less to more impairment). Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region (US/OUS), previous therapy (yes/no), baseline value, visit, and the interaction treatment-by-visit as fixed factors, covariance structure = unstructured.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Analysis Population Description: All participants who received at least one dose of study drug who had baseline and at least one post-baseline DLQI observation.

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	48	51	49
Units: score on a scale				
least squares mean (standard error)	-1.07 (± 0.69)	-9.19 (± 0.71)	-10.18 (± 0.69)	-9.64 (± 0.70)

Statistical analyses

Statistical analysis title	Mean Change From Baseline on DLQI Total Score
Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-8.12

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.05
upper limit	-6.19
Variability estimate	Standard error of the mean
Dispersion value	0.98

Statistical analysis title	Mean Change From Baseline on DLQI Total Score
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-9.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.02
upper limit	-7.2
Variability estimate	Standard error of the mean
Dispersion value	0.97

Statistical analysis title	Mean Change From Baseline on DLQI Total Score
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-8.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	-6.65
Variability estimate	Standard error of the mean
Dispersion value	0.98

Secondary: Mean Change from Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary

(MCS) Scores	
End point title	Mean Change from Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). MCS consisted of social functioning, vitality, mental health, and role-emotional scales. PCS consisted of physical functioning, bodily pain, role-physical, and general health scales. Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. Least Squares Mean (LS Mean) was calculated using Analysis of covariance (ANCOVA) model with treatment, geographic region (US/OUS), and previous therapy (yes/no) as fixed factors and baseline value as covariate.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Analysis Population Description: All participants who received at least one dose of study drug with a baseline value and at least 1 post-baseline value.

End point values	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W	Induction: 300 mg Mirikizumab Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	48	51	49
Units: score on a scale				
least squares mean (standard error)				
MCS	0.28 (± 0.87)	2.39 (± 0.90)	2.74 (± 0.88)	1.52 (± 0.88)
PCS	1.23 (± 0.84)	4.58 (± 0.88)	4.40 (± 0.85)	5.09 (± 0.85)

Statistical analyses

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS

Statistical analysis description:

Mental Component Summary (MCS).

Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.009
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	4.56
Variability estimate	Standard error of the mean
Dispersion value	1.24

Notes:

[7] - Mental Component Summary (MCS).

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS
Statistical analysis description: Mental Component Summary (MCS).	
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	4.88
Variability estimate	Standard error of the mean
Dispersion value	1.22

Notes:

[8] - Mental Component Summary (MCS)

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS
Statistical analysis description: Mental Component Summary (MCS).	
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.087
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	3.68
Variability estimate	Standard error of the mean
Dispersion value	1.24

Notes:
[9] - Mental Component Summary (MCS).

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS
Statistical analysis description:	
Physical Component Summary	
Comparison groups	Induction: Placebo v Induction: 30 mg Mirikizumab Q8W
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	5.72
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:
[10] - Physical Component Summary

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS
Statistical analysis description:	
Physical Component Summary	
Comparison groups	Induction: Placebo v Induction:100 mg Mirikizumab Q8W
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	5.49
Variability estimate	Standard error of the mean
Dispersion value	1.18

Notes:
[11] - Physical Component Summary

Statistical analysis title	Mean Change From Baseline on SF-36 PCS and MCS
Statistical analysis description:	
Physical Component Summary	
Comparison groups	Induction: Placebo v Induction: 300 mg Mirikizumab Q8W

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	6.21
Variability estimate	Standard error of the mean
Dispersion value	1.19

Notes:

[12] - Physical Component Summary

Secondary: Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline through Week 104

End point title	Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline through Week 104

End point description:

Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline Through Week 104.

Analysis Population Description: All participants who received at least one dose of study drug and had evaluable PK data.
The geometric coefficient of variation presented is "%" and not "±". Due to system limitation, the system populates data field with "±".

End point type	Secondary

End point timeframe:

Week 0, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 52, Week 56, Week 64, Week 72, Week 80, Week 88, Week 96, Week 100, Week 104

End point values	30 mg mirikizumab Q8W To 30 mg mirikizumab PRN	100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN	300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN	Placebo to 300 mg Mirikizumab Q8W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	23	33	50
Units: nanogram*hour per milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	3.22 (± 46.33)	8.94 (± 79.19)	22.96 (± 55.80)	46.4 (± 62.8)

End point values	30 mg mirikizumab Q8W to 300	100 mg Mirikizumab Q8W to 300	300 mg mirikizumab SC Q8W To	

	mg mirikizumab Q8W	mg MirikizumabQ8W	300 mg mirikizumab SC Q8W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	34	21	15	
Units: nanogram*hour per milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	34.83 (± 92.13)	47.66 (± 70.08)	51.30 (± 43.54)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Up To 120 Weeks

Adverse event reporting additional description:

All participants who received at least one dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Induction: Placebo

Reporting group description:

Induction: Participants received placebo SC Q8W during Induction period.

Reporting group title	Induction: 30 mg Mirikizumab Q8W

Reporting group description:

Induction: Participants received 30 mg mirikizumab Q8W during Induction period.

Reporting group title	Induction:100 mg Mirikizumab Q8W

Reporting group description:

Induction: Participants received 100 mg mirikizumab SC Q8W during Induction period.

Reporting group title	Induction: 300 mg Mirikizumab Q8W

Reporting group description:

Induction: Participants received 300 mg mirikizumab SC Q8W during Induction period.

Reporting group title	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN

Reporting group description:

Maintenance:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants who had ≥ PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN

Reporting group description:

Maintenance:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Reporting group title	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had ≥ PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Reporting group title	Maintenance: Placebo to 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had

received placebo during induction period.

Reporting group title	Maintenance: 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Reporting group title	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Reporting group title	Maintenance: 300 mg Mirikizumab Q8W

Reporting group description:

Maintenance:

Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

Reporting group title	300 mg Mirikizumab Q8W-Rescue

Reporting group description:

Participants received 300 mg Q8W mirikizumab during rescue.

Reporting group title	30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN-Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN-Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN-Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	Placebo to 300 mg Mirikizumab Q8W-Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

Reporting group title	100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up

Reporting group description:

100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up.

Serious adverse events	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 52 (1.92%)	1 / 51 (1.96%)	0 / 51 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraocular melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm malignant			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	0 / 51 (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
Infections and infestations			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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	Induction: 300 mg Mirikizumab Q8W	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN
Total subjects affected by serious			

adverse events			
subjects affected / exposed	1 / 51 (1.96%)	1 / 15 (6.67%)	2 / 30 (6.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraocular melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm malignant			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
femur fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			

nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (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
Infections and infestations			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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	Maintenance: 300 mg Mirikizumab	Maintenance: Placebo to 300 mg	Maintenance: 30 mg Mirikizumab Q8W to

	Q8W to 300 mg Mirikizumab PRN	Mirikizumab Q8W	300 mg Mirikizumab Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 34 (2.94%)	2 / 50 (4.00%)	2 / 34 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraocular melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm malignant			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
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			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (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			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
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			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
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 22.0			

subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W	Maintenance: 300 mg Mirikizumab Q8W	300 mg Mirikizumab Q8W-Rescue
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 21 (9.52%)	3 / 15 (20.00%)	1 / 10 (10.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraocular melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung neoplasm malignant			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (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 disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (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
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (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
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (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

pyelonephritis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN-Follow-up	100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN-Follow-up	300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN-Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraocular melanoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lung neoplasm malignant			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo to 300 mg Mirikizumab Q8W-Follow-up	30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up	100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
intraocular melanoma			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
lung neoplasm malignant			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Injury, poisoning and procedural complications			
femur fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Surgical and medical procedures			
nasal septal operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Gastrointestinal disorders			
enlarged uvula			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Psychiatric disorders			
suicidal ideation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Infections and infestations			
endocarditis bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
erysipelas			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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

pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
pyelonephritis acute			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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

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

Non-serious adverse events	Induction: Placebo	Induction: 30 mg Mirikizumab Q8W	Induction:100 mg Mirikizumab Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 52 (36.54%)	24 / 51 (47.06%)	19 / 51 (37.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
occurrences (all)	0	0	3
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 52 (3.85%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	2	1	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	3 / 51 (5.88%)	3 / 51 (5.88%)
occurrences (all)	2	15	14
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[3]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	1	1	2
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 52 (3.85%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	2	1	1
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	1	1	1
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	1	1	1
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 52 (13.46%)	5 / 51 (9.80%)	6 / 51 (11.76%)
occurrences (all)	8	7	8
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	3	0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 52 (1.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 52 (3.85%)	6 / 51 (11.76%)	3 / 51 (5.88%)
occurrences (all)	2	6	3
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 52 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Induction: 300 mg Mirikizumab Q8W	Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN	Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 51 (37.25%)	13 / 15 (86.67%)	20 / 30 (66.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 51 (5.88%)	0 / 15 (0.00%)	3 / 30 (10.00%)
occurrences (all)	3	0	3
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 51 (3.92%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	9	9	6
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	4	0	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 36 (0.00%)	0 / 11 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 36 (0.00%)	0 / 11 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	2 / 15 (13.33%)	1 / 30 (3.33%)
occurrences (all)	0	2	1
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	7	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	5	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	2
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	1 / 15 (6.67%)	2 / 30 (6.67%)
occurrences (all)	1	1	5
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	2
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 51 (5.88%)	2 / 15 (13.33%)	0 / 30 (0.00%)
occurrences (all)	3	2	0
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	2
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 51 (15.69%)	3 / 15 (20.00%)	3 / 30 (10.00%)
occurrences (all)	10	8	3
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 51 (1.96%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 51 (3.92%)	2 / 15 (13.33%)	5 / 30 (16.67%)
occurrences (all)	3	2	6
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 51 (0.00%)	0 / 15 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2

Non-serious adverse events	Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN	Maintenance: Placebo to 300 mg Mirikizumab Q8W	Maintenance: 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 34 (67.65%)	38 / 50 (76.00%)	28 / 34 (82.35%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 34 (8.82%)	4 / 50 (8.00%)	3 / 34 (8.82%)
occurrences (all)	4	4	3
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	4 / 50 (8.00%)	3 / 34 (8.82%)
occurrences (all)	3	92	67
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	0 / 34 (0.00%)
occurrences (all)	0	6	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	2 / 34 (5.88%)
occurrences (all)	0	2	2
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
ovarian cyst			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 26 (0.00%)	0 / 40 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 26 (0.00%)	0 / 40 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	0 / 50 (0.00%)	5 / 34 (14.71%)
occurrences (all)	2	0	8
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 34 (2.94%)	3 / 50 (6.00%)	2 / 34 (5.88%)
occurrences (all)	1	3	2
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	2 / 34 (5.88%)
occurrences (all)	0	2	5
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	3 / 50 (6.00%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	2 / 34 (5.88%)
occurrences (all)	0	2	2
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	2 / 50 (4.00%)	1 / 34 (2.94%)
occurrences (all)	1	2	1
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	4
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 34 (8.82%)	3 / 50 (6.00%)	2 / 34 (5.88%)
occurrences (all)	3	4	4
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	2
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	2 / 50 (4.00%)	1 / 34 (2.94%)
occurrences (all)	1	2	1
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	1 / 34 (2.94%)
occurrences (all)	0	3	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	2	0	1
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	3
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	3 / 50 (6.00%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 34 (8.82%)	1 / 50 (2.00%)	2 / 34 (5.88%)
occurrences (all)	3	4	2
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	3 / 50 (6.00%)	8 / 34 (23.53%)
occurrences (all)	0	3	10
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	1 / 50 (2.00%)	2 / 34 (5.88%)
occurrences (all)	2	1	2
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	1 / 34 (2.94%)
occurrences (all)	0	3	1
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 34 (8.82%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	3 / 50 (6.00%)	2 / 34 (5.88%)
occurrences (all)	2	3	2
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 34 (20.59%)	15 / 50 (30.00%)	12 / 34 (35.29%)
occurrences (all)	10	26	25
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	2 / 50 (4.00%)	1 / 34 (2.94%)
occurrences (all)	1	2	1

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	2 / 50 (4.00%)	3 / 34 (8.82%)
occurrences (all)	0	2	3
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	2	1	1
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	8 / 50 (16.00%)	3 / 34 (8.82%)
occurrences (all)	2	9	7
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 34 (8.82%)	4 / 50 (8.00%)	1 / 34 (2.94%)
occurrences (all)	3	5	1
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 34 (5.88%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	2	1	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	1 / 50 (2.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 34 (2.94%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 34 (0.00%)	0 / 50 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W	Maintenance: 300 mg Mirikizumab Q8W	300 mg Mirikizumab Q8W-Rescue
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 21 (85.71%)	13 / 15 (86.67%)	9 / 10 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 21 (23.81%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	5	1	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
sinus operation			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 15 (0.00%)	2 / 10 (20.00%)
occurrences (all)	31	0	39
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 21 (9.52%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 21 (14.29%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 15 (13.33%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 15 (13.33%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 21 (14.29%)	1 / 15 (6.67%)	1 / 10 (10.00%)
occurrences (all)	4	1	1
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 21 (14.29%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	2	1	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 21 (9.52%)	3 / 15 (20.00%)	0 / 10 (0.00%)
occurrences (all)	2	4	0
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 21 (14.29%)	1 / 15 (6.67%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 21 (23.81%)	5 / 15 (33.33%)	2 / 10 (20.00%)
occurrences (all)	13	12	3
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	1 / 10 (10.00%)
occurrences (all)	0	1	2
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 21 (14.29%)	2 / 15 (13.33%)	0 / 10 (0.00%)
occurrences (all)	3	2	0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 21 (4.76%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 21 (23.81%)	1 / 15 (6.67%)	1 / 10 (10.00%)
occurrences (all)	6	2	1
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 15 (13.33%)	0 / 10 (0.00%)
occurrences (all)	2	3	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 21 (4.76%)	0 / 15 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 15 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 15 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN-Follow-up	100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN-Follow-up	300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN-Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo to 300 mg Mirikizumab Q8W-Follow-up	30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up	100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 2 (50.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
menorrhagia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
prostatomegaly			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
scrotal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[6]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract congestion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[8]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
myocardial infarction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

cataract			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
abdominal tenderness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
duodenal ulcer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
stasis dermatitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

psoriatic arthropathy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
erythema migrans			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
localised infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

otitis externa			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urethritis chlamydial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[9]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Notes:

[1] - 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.
[2] - 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.
[3] - 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.
[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.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed 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.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed 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.
[9] - 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