Clinical trial results:
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF LEBRIKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS

Summary

EudraCT number	2019-002933-12
Trial protocol	DE BG IT
Global end of trial date	28 April 2022

Results information

Result version number	v2 (current)
This version publication date	11 May 2023
First version publication date	27 July 2022
Version creation reason	• New data added to full data set Full Data

Trial information

Trial identification

Sponsor protocol code	J2T-DM-KGAC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17802

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)	Yes
EMA paediatric investigation plan number(s)	EMEA-002536-PIP01-18
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	28 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a randomized, double-blind, placebo-controlled, parallel-group study which is 52 weeks in duration. The study is designed to confirm the safety and efficacy of lebrikizumab as monotherapy for treatment of moderate-to-severe atopic dermatitis utilizing a 16-week induction treatment period and a 36-week long-term maintenance treatment period.

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	29 October 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 58
Country: Number of subjects enrolled	Singapore: 19
Country: Number of subjects enrolled	United States: 185
Country: Number of subjects enrolled	Taiwan: 60
Country: Number of subjects enrolled	Ukraine: 11
Country: Number of subjects enrolled	Mexico: 9
Country: Number of subjects enrolled	Bulgaria: 22
Country: Number of subjects enrolled	Germany: 81
Worldwide total number of subjects	445
EEA total number of subjects	103

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	50
Adults (18-64 years)	362
From 65 to 84 years	33
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were randomly assigned to either 250 mg lebrikizumab Q2W or placebo; At week (Wk) 16, participants who responded to treatment, defined as having an IGA of 0 or 1 or a 75% reduction in EASI-75 from Baseline to Wk 16 entered Maintenance Period; were re-randomized (2:2:1) to: lebrikizumab 250 mg Q2W, lebrikizumab 250 mg Q4W, or placebo

Pre-assignment

Screening details:

(Continued) Induction non-responder; participants who do not achieve IGA of 0 or 1 or EASI-75 at Week 16 and maintenance non-responders; those not maintaining an EASI-50 response at week 24, 32, 40, and 48 following week 16 re-randomization were assigned to Escape Arm received lebrikizumab 250 mg as open-label treatment Q2W through Week 52.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction - Placebo

Arm description:

Induction Period (Baseline-Week 16):
Two subcutaneous (SC) injections of Placebo as a loading dose at Baseline and Week 2 followed by a single injection every 2 weeks (Q2W) from Week 4 until Week 14.

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:

Two subcutaneous injections of Placebo as a loading dose at Baseline and Week 2 followed by a single injection every 2 weeks (Q2W) from Week 4 until Week 14.

Arm title	Induction - Lebrikizumab Q2W

Arm description:

Induction Period (Baseline-Week 16):
500 milligram (mg) Lebrikizumab (2 x 250 mg) SC injections as a loading dose at Baseline and Week 2 visits followed by a single 250 mg Lebrikizumab injection Q2W from Week 4 until Week 14.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 250 mg of Lebrikizumab administered as subcutaneous injection.

Number of subjects in period 1	Induction - Placebo	Induction - Lebrikizumab Q2W
Started	150	295
Received at Least One Dose of Study Drug	149	295
Completed	133	273
Not completed	17	22
Consent withdrawn by subject	6	4
Participant Missed Study Visits	-	1
Adverse event, non-fatal	4	6
Due to Epidemic/Pandemic	1	4
Lost to follow-up	2	-
Lack of efficacy	4	1
Protocol deviation	-	6

Period 2

Period 2 title	Maintenance Blinded Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Maintenance - Placebo Responder/Placebo

Arm description:

Maintenance Secondary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50. Two placebo SC injections as loading dose on Week 16 and Week 18.

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

Dosage and administration details:

Participants received subcutaneous Injection of Placebo.

Arm title	Maintenance - Placebo Responder/Lebrikizumab 250 Q4W

Arm description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.
For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two placebo injections on Week 18.

Arm type	Experimental

Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Two 250 mg Lebrikizumab SC injection as maintenance loading dose on Week 16 and two placebo SC injections on Week 18. One 250 mg Lebrikizumab SC injection Every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.

Arm title	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W

Arm description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg Lebrikizumab SC injection Q2W.

Arm title	Maintenance - Lebrikizumab Responder/Placebo

Arm description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50.
Two placebo SC injections as loading dose on Week 16 and Week 18.

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

Dosage and administration details:

One SC injection of Placebo Q2W.

Arm title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W

Arm description:

Maintenance Primary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.
To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. Two placebo injections on Week 18.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

One 250 mg Lebrikizumab SC injection and one placebo SC injection as maintenance loading dose on Week 16 and two placebo SC injections on Week 18. One 250 mg Lebrikizumab SC injection Every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.

Arm title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W

Arm description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg Lebrikizumab SC injection Q2W.

Number of subjects in period 2[1]	Maintenance - Placebo Responder/Placebo	Maintenance - Placebo Responder/Lebrikizumab 250 Q4W	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W
Started	5	9	11
Received at Least One Dose of Study Drug	5	9	11
Completed	4	6	9
Not completed	1	3	2
Consent withdrawn by subject	-	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Sponsor Decision	1	1	1
Entered Escape Arm	-	1	-
Lost to follow-up	-	1	-
Lack of efficacy	-	-	-

Number of subjects in period 2[1]	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Started	30	59	59
Received at Least One Dose of Study Drug	30	59	59
Completed	22	51	42
Not completed	8	8	17
Consent withdrawn by subject	2	-	4
Physician decision	-	1	-
Adverse event, non-fatal	1	2	1
Sponsor Decision	1	4	6
Entered Escape Arm	3	1	6
Lost to follow-up	-	-	-

Lack of efficacy	1	-	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who responded to treatment, defined as and IGA of 0 or 1 or a 75% reduction in EASI from baseline to Week 16, entered the Maintenance Period and re-randomized to the following treatment groups: lebrikizumab 250 mg Q2W, lebrikizumab 250 mg Q4W, or placebo Q2W.

Period 3

Period 3 title	Maintenance Open Label Escape Arm
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Escape Arm Wk 16 - Maintenance OL- PBO/Leb 250 Q2W

Arm description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50 in an open-label fashion. For participants who received placebo in the Induction Period, the loading dose is: Two 250 mg Lebrikizumab SC injection on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg Lebrikizumab Q2W.

Arm title	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W

Arm description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50 in an open-label fashion. To maintain the loading dose blind, for participants who received Lebrikizumab in the Induction Period, the loading dose is: One 250 mg Lebrikizumab SC injection and one placebo on Week16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Maintenance Escape Period (Week 16 to Week 52): 250 mg Lebrikizumab SC injection Q2W.

Arm title	Escape Arm Wk 24-48 - Maintenance OL - Leb 250 Q2W

Arm description:

Escape Arm Week 24 to 48 - Maintenance Open Label Lebrikizumab 250 Q2W.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	LY3650150, DRM06
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Maintenance Escape Period (Week 24 to Week 48): 250 mg Lebrikizumab Q2W.

Number of subjects in period 3	Escape Arm Wk 16 - Maintenance OL- PBO/Leb 250 Q2W	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W	Escape Arm Wk 24-48 - Maintenance OL - Leb 250 Q2W
Started	108	125	11
Received at Least One Dose of Study Drug	108	125	11
Completed	85	83	8
Not completed	23	42	3
Consent withdrawn by subject	4	9	1
Participant Missed Study Visits	-	1	-
Adverse event, non-fatal	3	3	-
Sponsor Decision	-	1	-
Lost to follow-up	-	1	-
Lack of efficacy	16	27	2

Baseline characteristics

Reporting groups	
Reporting group title	Induction - Placebo
Reporting group description:	
Induction Period (Baseline-Week 16): Two subcutaneous (SC) injections of Placebo as a loading dose at Baseline and Week 2 followed by a single injection every 2 weeks (Q2W) from Week 4 until Week 14.	
Reporting group title	Induction - Lebrikizumab Q2W
Reporting group description:	
Induction Period (Baseline-Week 16): 500 milligram (mg) Lebrikizumab (2 x 250 mg) SC injections as a loading dose at Baseline and Week 2 visits followed by a single 250 mg Lebrikizumab injection Q2W from Week 4 until Week 14.	

Reporting group values	Induction - Placebo	Induction - Lebrikizumab Q2W	Total
Number of subjects	150	295	445
Age categorical Units: Subjects			
<=18 years	17	33	50
Between 18 and 65 years	123	239	362
>=65 years	10	23	33
Gender categorical Units: Subjects			
Female	79	147	226
Male	71	148	219
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	3	5
Asian	44	78	122
Native Hawaiian or Other Pacific Islander	1	2	3
Black or African American	10	26	36
White	89	181	270
More than one race	3	4	7
Unknown or Not Reported	1	1	2
Region of Enrollment Units: Subjects			
Canada	16	42	58
Singapore	8	11	19
United States	64	121	185
Taiwan	21	39	60
Ukraine	3	8	11
Mexico	3	6	9
Bulgaria	7	15	22
Germany	28	53	81

End points reporting groups

Reporting group title	Induction - Placebo

Reporting group description:

Induction Period (Baseline-Week 16):
Two subcutaneous (SC) injections of Placebo as a loading dose at Baseline and Week 2 followed by a single injection every 2 weeks (Q2W) from Week 4 until Week 14.

Reporting group title	Induction - Lebrikizumab Q2W

Reporting group description:

Induction Period (Baseline-Week 16):
500 milligram (mg) Lebrikizumab (2 x 250 mg) SC injections as a loading dose at Baseline and Week 2 visits followed by a single 250 mg Lebrikizumab injection Q2W from Week 4 until Week 14.

Reporting group title	Maintenance - Placebo Responder/Placebo

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50. Two placebo SC injections as loading dose on Week 16 and Week 18.

Reporting group title	Maintenance - Placebo Responder/Lebrikizumab 250 Q4W

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.
For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two placebo injections on Week 18.

Reporting group title	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18.

Reporting group title	Maintenance - Lebrikizumab Responder/Placebo

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50.
Two placebo SC injections as loading dose on Week 16 and Week 18.

Reporting group title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50.
To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. Two placebo injections on Week 18.

Reporting group title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18.

Reporting group title	Escape Arm Wk 16 - Maintenance OL- PBO/Leb 250 Q2W

Reporting group description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50 in an open-label fashion. For participants who received placebo in the Induction Period, the loading dose is: Two 250 mg Lebrikizumab SC injection on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an

EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Reporting group title	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W

Reporting group description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50 in an open-label fashion. To maintain the loading dose blind, for participants who received Lebrikizumab in the Induction Period, the loading dose is: One 250 mg Lebrikizumab SC injection and one placebo on Week16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Reporting group title	Escape Arm Wk 24-48 - Maintenance OL - Leb 250 Q2W

Reporting group description:

Escape Arm Week 24 to 48 - Maintenance Open Label Lebrikizumab 250 Q2W.

Subject analysis set title	Maintenance 250 mg Lebrikizumab Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

250 mg Lebrikizumab administered SC injection Q4W.

Subject analysis set title	Maintenance 250 mg Leb Q2W and 250 mg Leb escape Q2W
Subject analysis set type	Per protocol

Subject analysis set description:

250 mg Lebrikizumab (Leb) administered SC injection Q2W.

Primary: Percentage of Participants With an Investigator Global Assessment (IGA) Score of 0 or 1 and a Reduction ≥2 Points From Baseline to Week 16

End point title	Percentage of Participants With an Investigator Global Assessment (IGA) Score of 0 or 1 and a Reduction ≥2 Points From Baseline to Week 16

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to Good Clinical Practice (GCP) issues. Markov Chain Monte Carlo Multiple Imputation (MCMC-MI) was used to handle missing data.

End point type	Primary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	10.8 (5.7 to 15.9)	33.2 (27.5 to 38.9)		

Statistical analyses

Statistical analysis title	Percentage of Participants With an Investigator G
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000004
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	21.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.2
upper limit	29.6

Primary: Percentage of Participants Achieving Eczema Area And Severity Index (EASI-75) (≥75% Reduction in EASI Score) From Baseline to Week 16

End point title	Percentage of Participants Achieving Eczema Area And Severity Index (EASI-75) (≥75% Reduction in EASI Score) From Baseline to Week 16

End point description:

The EASI assesses objective physician estimates of 2 dimensions of AD - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Primary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	18.1 (11.7 to 24.5)	52.1 (46.1 to 58.0)		

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving Eczema Area
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	33.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.4
upper limit	42.2

Secondary: Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 2

End point title	Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 2

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 0.0)	0.7 (-0.3 to 1.7)		

Statistical analyses

Statistical analysis title	Percentage of participants with an IGA score of 0
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.308463
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	1.7

Secondary: Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 4

End point title	Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 4

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 4

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	1.4 (0.0 to 3.3)	9.0 (5.6 to 12.4)		

Statistical analyses

Statistical analysis title	Percentage of participants with an IGA score of 0
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001607
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	12

Secondary: Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 16

End point title	Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 16

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	10.8 (5.7 to 15.9)	33.2 (27.5 to 38.9)		

Statistical analyses

Statistical analysis title	Percentage of participants with an IGA score of 0
Comparison groups	Induction - Lebrikizumab Q2W v Induction - Placebo

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000004
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	21.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.2
upper limit	29.6

Secondary: Percentage of participants achieving EASI-90 (≥90% reduction in EASI score) from Baseline to Week 16

End point title	Percentage of participants achieving EASI-90 (≥90% reduction in EASI score) from Baseline to Week 16

End point description:

The EASI assesses objective physician estimates of 2 dimensions of AD-disease extent and clinical signs affected: 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0=none, absent; 1=mild; 2=moderate; 3=severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	9.5 (4.6 to 14.3)	30.7 (25.2 to 36.2)		

Statistical analyses

Statistical analysis title	Percentage of participants achieving EASI-90 (≥90
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000008
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	20.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.3
upper limit	28.1

Secondary: Percentage change in Pruritus Numerical Rating Scale (NRS) score from Baseline to Week 16

End point title	Percentage change in Pruritus Numerical Rating Scale (NRS) score from Baseline to Week 16

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable." Least Squares (LS) Mean was calculated using analysis of covariance (ANCOVA) model with treatment and randomization strata (region, disease severity, age) as fixed factors and baseline value as covariate. All randomized participants, with a Baseline Pruritus NRS score >0, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage change				
least squares mean (standard error)	-9.02 (± 3.868)	-36.56 (± 3.321)		

Statistical analyses

Statistical analysis title	Percentage change in Pruritus Numerical Rating Sc
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-27.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.9
upper limit	-20.2

Secondary: Percentage of participants with a Pruritus NRS score of ≥4-points at Baseline who achieve a ≥4-point reduction in Pruritus NRS score from Baseline to Week 16

End point title	Percentage of participants with a Pruritus NRS score of ≥4-points at Baseline who achieve a ≥4-point reduction in Pruritus NRS score from Baseline to Week 16

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Baseline Pruritus NRS score ≥4, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	253		
Units: percentage of participants				
number (confidence interval 95%)	11.5 (6 to 16.9)	39.8 (33.6 to 46.0)		

Statistical analyses

Statistical analysis title	Pruritus NRS score of ≥4-points
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	387
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	28.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	20
upper limit	36.5

Secondary: Percentage of participants with a Pruritus NRS score of ≥5-points at Baseline who achieve a ≥4-point reduction in Pruritus NRS score from Baseline to Week 16

End point title	Percentage of participants with a Pruritus NRS score of ≥5-points at Baseline who achieve a ≥4-point reduction in Pruritus NRS score from Baseline to Week 16

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with Baseline Pruritus NRS score ≥ 5, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	234		
Units: percentage of participants				
number (confidence interval 95%)	11.8 (6 to 17.6)	41.6 (35.1 to 48.1)		

Statistical analyses

Statistical analysis title	Pruritus NRS score of ≥5-points
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	21
upper limit	38.4

Secondary: Percentage change in EASI score from Baseline to Week 16

End point title	Percentage change in EASI score from Baseline to Week 16

End point description:

The EASI assesses objective physician estimates of 2 dimensions of AD - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percent change				
least squares mean (standard error)	-27.96 (± 3.893)	-61.53 (± 3.300)		

Statistical analyses

Statistical analysis title	EASI score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-33.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.2
upper limit	-26

Secondary: Change From Baseline in Percent Body Surface Area (BSA) at Week 16

End point title	Change From Baseline in Percent Body Surface Area (BSA) at Week 16

End point description:

The BSA affected by AD will be assessed for 4 separate body regions: head and neck, trunk (including genital region), upper extremities, and lower extremities (including the buttocks). Each body region will be assessed for disease extent ranging from 0% to 100% involvement. BSA was calculated using the participant's palm using the 1% rule, 1 palm was equivalent to 1% with estimates of the number of palms it takes to cover the affected AD area. Percent of BSA for a body region was calculated as=total number of palms in a body region*% surface area equivalent to 1 palm. Overall percent BSA of all 4 body regions ranges from 0% to 100 % with higher values representing greater severity of AD. All randomized participants, with observed BSA data, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	213		
Units: percentage of BSA				
least squares mean (standard error)	-14.0 (± 1.94)	-30.2 (± 1.33)		

Statistical analyses

Statistical analysis title	Percent BSA
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	290
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.3
upper limit	-12

Secondary: Percentage of participants achieving EASI-90 from Baseline to Week 4

End point title	Percentage of participants achieving EASI-90 from Baseline to Week 4

End point description:

The EASI assesses objective physician estimates of 2 dimensions of AD - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). All randomized participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 4

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percentage of participants				
number (confidence interval 95%)	1.5 (-0.5 to 3.5)	6.3 (3.4 to 9.2)		

Statistical analyses

Statistical analysis title	EASI-90
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022921
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	8.4

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) at Week 16

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) at Week 16

End point description:

The DLQI is a 10-item, validated questionnaire used to assess the impact of skin disease on the quality of life of an affected person. The 10 questions cover the following topics: symptoms, embarrassment, shopping and home care, clothes, social and leisure, sport, work or study, close relationships, sex, and treatment, over the previous week. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. A high score is indicative of a poor quality of life. All randomized participants, with non-missing baseline DLQI score, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	218		
Units: score on a scale				
least squares mean (standard error)	-2.4 (± 1.17)	-7.3 (± 1.16)		

Statistical analyses

Statistical analysis title	Dermatology Life Quality Index (DLQI)
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	-3.5

Secondary: Percentage of participants achieving ≥4-point improvement in DLQI from Baseline to Week 16

End point title	Percentage of participants achieving ≥4-point improvement in DLQI from Baseline to Week 16

End point description:

The DLQI is a 10-item, validated questionnaire used to assess the impact of skin disease on the quality of life of an affected person. The 10 questions cover the following topics: symptoms, embarrassment, shopping and home care, clothes, social and leisure, sport, work or study, close relationships, sex, and treatment, over the previous week. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. A high score is indicative of a poor quality of life. All randomized participants, with non-missing baseline DLQI score, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	218		
Units: percentage of participants				
number (confidence interval 95%)	32.8 (24.1 to 41.4)	65.4 (59.0 to 71.9)		

Statistical analyses

Statistical analysis title	DLQI
Comparison groups	Induction - Lebrikizumab Q2W v Induction - Placebo

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	32.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.2
upper limit	43.6

Secondary: Percentage of participants with a DLQI total score of ≥4-point at baseline achieving ≥4-point improvement in DLQI from baseline to Week 16

End point title	Percentage of participants with a DLQI total score of ≥4-point at baseline achieving ≥4-point improvement in DLQI from baseline to Week 16

End point description:

The DLQI is a 10-item, validated questionnaire used to assess the impact of skin disease on the quality of life of an affected person. The 10 questions cover the following topics: symptoms, embarrassment, shopping and home care, clothes, social and leisure, sport, work or study, close relationships, sex, and treatment, over the previous week. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. A high score is indicative of a poor quality of life. All randomized participants, with a DLQI Total Score of ≥4-point at baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	115	215		
Units: percentage of participants				
number (confidence interval 95%)	33.6 (24.8 to 42.5)	66.3 (59.9 to 72.8)		

Statistical analyses

Statistical analysis title	DLQI total score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	33
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.2
upper limit	43.8

Secondary: Percentage change in Sleep-loss score from Baseline to Week 16

End point title	Percentage change in Sleep-loss score from Baseline to Week 16

End point description:

Sleep Loss due to interference of itch will be assessed by the participant. Participants rate their interference of itch on sleep based on a 5-point Likert scale [0 (not at all) to 4 (unable to sleep at all)]. Higher scores indicated a greater impact and worse outcome. Assessments will be recorded daily by the participant using an electronic diary. LS Mean was calculated using ANCOVA model with treatment, baseline value, and stratification factors of geographic region, age group, baseline IGA (3 versus 4) score as fixed factors. All randomized participants, with baseline sleep-loss score >0, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percent change				
least squares mean (standard error)	-11.29 (± 5.393)	-48.37 (± 4.590)		

Statistical analyses

Statistical analysis title	Sleep-loss score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-37.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.4
upper limit	-26.8

Secondary: Change from Baseline in Sleep-loss score at Week 16

End point title	Change from Baseline in Sleep-loss score at Week 16

End point description:

Sleep Loss due to interference of itch will be assessed by the participant. Participants rate their interference of itch on sleep based on a 5-point Likert scale [0 (not at all) to 4 (unable to sleep at all)]. Higher scores indicated a greater impact and worse outcome. Assessments will be recorded daily by the participant using an electronic diary. LS Mean was calculated using ANCOVA model with treatment, baseline value, and stratification factors of geographic region, age group, baseline IGA (3 versus 4) score as fixed factors. All randomized participants, with non-missing baseline Sleep-loss score, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: score on a scale				
least squares mean (standard error)	-0.35 (± 0.095)	-1.05 (± 0.080)		

Statistical analyses

Statistical analysis title	Sleep-loss score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	-0.5

Secondary: Percentage of participants with a Sleep-loss score ≥2 points at Baseline who achieve a ≥2 points reduction from Baseline to Week 16

End point title	Percentage of participants with a Sleep-loss score ≥2 points at Baseline who achieve a ≥2 points reduction from Baseline to Week 16

End point description:

Sleep Loss due to interference of itch will be assessed by the participant. Participants rate their interference of itch on sleep based on a 5-point Likert scale [0 (not at all) to 4 (unable to sleep at all)]. Higher scores indicated a greater impact and worse outcome. Assessments will be recorded daily by the participant using an electronic diary. All randomized participants, with baseline sleep-loss score ≥2 Points, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	161		
Units: percentage of participants				
number (confidence interval 95%)	8.2 (2.5 to 13.9)	28.0 (21.0 to 35.0)		

Statistical analyses

Statistical analysis title	Sleep-loss score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	258
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000571
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.6
upper limit	28.1

Secondary: Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 1

End point title	Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 1

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥4 Points at baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 1

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	253		
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 0.0)	0.4 (0.0 to 1.2)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	387
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.469221
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	1.2

Secondary: Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 2

End point title	Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 2

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥4 Points at Baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 2

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	253		
Units: percentage of participants				
number (confidence interval 95%)	0.7 (0.0 to 2.2)	3.6 (1.3 to 5.9)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	387
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113194
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	5.4

Secondary: Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 4

End point title	Percentage of participants with a Pruritus NRS score of ≥4 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 4

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥4 Points at Baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 4

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	253		
Units: percentage of participants				
number (confidence interval 95%)	3.0 (0.0 to 6.0)	16.8 (12.2 to 21.4)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	387
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00023
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	13.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	18.7

Secondary: Percentage of participants with a Pruritus NRS score of ≥5 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 1

End point title	Percentage of participants with a Pruritus NRS score of ≥5 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 1

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥5 Points at Baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 1

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	234		
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 0.0)	0.4 (0.0 to 1.3)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.46816
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	1.3

Secondary: Percentage of participants with a Pruritus NRS score of ≥5 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 2

End point title	Percentage of participants with a Pruritus NRS score of ≥5 points at Baseline who achieve a ≥4-point reduction from Baseline to Week 2

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥5 Points at Baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 2

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	234		
Units: percentage of participants				
number (confidence interval 95%)	0.8 (0.0 to 2.4)	3.9 (1.4 to 6.3)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11577
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	5.8

Secondary: Percentage Change in SCORing Atopic Dermatitis (SCORAD) from Baseline to Week 16

End point title	Percentage Change in SCORing Atopic Dermatitis (SCORAD) from Baseline to Week 16

End point description:

SCORAD is validated tool for assessing the extent and intensity of AD, it consists of 3 components: A=extent of AD as a percentage of each defined body area and reported as sum of all areas, with maximum score of 100%. B=severity of 6 specific symptoms of AD (redness, swelling, oozing/crusting, excoriation, skin thickening/lichenification, dryness) assessed using following scale: none=0, mild=1, moderate=2, or severe=3 for maximum of 18 total points. C=subjective assessment of itch and sleeplessness recorded by participant on visual analog scale (VAS), where 0=no itch/no sleeplessness and 10=worst imaginable itch/sleeplessness with maximum score of 20. SCORAD total score is calculated: A/5+7*B/2+ C to give total score range of 0 to 103, where 0=no disease to 103=severe disease. All randomized participants, with baseline SCORAD >0, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: percent change				
least squares mean (standard error)	-13.81 (± 3.197)	-44.57 (± 2.677)		

Statistical analyses

Statistical analysis title	SCORing Atopic Dermatitis (SCORAD)
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W

Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-30.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.93
upper limit	-24.59

Secondary: Pharmacokinetics (PK): Trough Serum Concentrations of Lebrikizumab in Maintenance Period (C-trough)

End point title	Pharmacokinetics (PK): Trough Serum Concentrations of Lebrikizumab in Maintenance Period (C-trough)

End point description:

C-trough was the concentration of study drug in the blood immediately before the next dose was administered. Trough serum concentration of Lebrikizumab was assessed at predose week 52. All participants who received 250 mg Q2W or 250 mg Q4W in the Maintenance Period and had evaluable PK data at Week 52. The 250 mg Q2W PK population also includes participants from the Escape Arm (Induction period non-responders and Maintenance Period non-responders who received open-label 250 mg Q2W dosing).

End point type	Secondary

End point timeframe:

Predose at Week 52

End point values	Maintenance 250 mg Lebrikizumab Q4W	Maintenance 250 mg Leb Q2W and 250 mg Leb escape Q2W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	206		
Units: micrograms/milliliter (µg/mL)				
arithmetic mean (standard deviation)	46.7 (± 24.8)	90.5 (± 40.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants from those re-randomized having achieved EASI-75 at Week 16 who continue to exhibit EASI-75 at Week 52 (EASI-75 calculated relative to baseline EASI score)

End point title	Percentage of participants from those re-randomized having achieved EASI-75 at Week 16 who continue to exhibit EASI-75 at Week 52 (EASI-75 calculated relative to baseline EASI

	score)

End point description:

The EASI assesses objective physician estimates of 2 dimensions of AD - disease extent, i.e., percentage of skin affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI-75 score was obtained by weight-averaging these 4 scores and will range from 0 (none) to 72 (severe). All participants who were randomized to Lebrikizumab 250 mg Q2W at Baseline Visit and re-randomized to Lebrikizumab 250 mg Q2W, Lebrikizumab 250 mg Q4W or placebo at Week 16 and received at least 1 dose of study treatment during the maintenance period and had evaluable EASI-75 data at week 52.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	27	53	51	
Units: percentage of participants				
number (confidence interval 95%)	72.0 (53.0 to 91.0)	84.7 (73.0 to 96.4)	77.4 (65.4 to 89.4)	

Statistical analyses

Statistical analysis title	EASI-75
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.238245
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	12.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	35.1

Statistical analysis title	EASI-75
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W

Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.612427
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.8
upper limit	27.3

Secondary: Percentage of participants from those re-randomized having achieved IGA 0 or 1 and a ≥2-point improvement from Baseline at Week 16 who continue to exhibit an IGA 0 or 1 and a ≥2-point improvement from Baseline at Week 52

End point title	Percentage of participants from those re-randomized having achieved IGA 0 or 1 and a ≥2-point improvement from Baseline at Week 16 who continue to exhibit an IGA 0 or 1 and a ≥2-point improvement from Baseline at Week 52

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All participants who were randomized to Lebrikizumab 250 mg Q2W at Baseline Visit and re-randomized to Lebrikizumab 250 mg Q2W, Lebrikizumab 250 mg Q4W or placebo at Week 16 and received at least 1 dose of study treatment during the maintenance period and had evaluable IGA data at week 52.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	32	32	
Units: percentage of participants				
number (confidence interval 95%)	49.8 (23.7 to 75.8)	80.6 (65.9 to 95.3)	64.6 (47.2 to 82.0)	

Statistical analyses

Statistical analysis title	IGA score of 0 or 1
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033876
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	32.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	62.5

Statistical analysis title	IGA score of 0 or 1
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.407417
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	13.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.5
upper limit	44.3

Secondary: Percentage of participants from those with a Pruritus NRS of ≥4-points at baseline re-randomized having achieved ≥4-point reduction from baseline at Week 16 who continue to exhibit ≥4-point reduction from baseline at Week 52

End point title	Percentage of participants from those with a Pruritus NRS of ≥4-points at baseline re-randomized having achieved ≥4-point reduction from baseline at Week 16 who continue to exhibit ≥4-point reduction from baseline at Week 52

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All participants who were randomized to Lebrikizumab 250 mg Q2W at Baseline Visit and re-randomized to Lebrikizumab 250 mg Q2W, Lebrikizumab 250 mg Q4W or placebo at Week 16 and received at least 1 dose of study treatment during the maintenance period and had evaluable data at week 52.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	36	23	
Units: percentage of participants				
number (confidence interval 95%)	67.6 (38.6 to 96.7)	88.1 (77.1 to 99.1)	90.3 (77.3 to 103.2)	

Statistical analyses

Statistical analysis title	Pruritus NRS
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.159281
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	20.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.4
upper limit	52

Statistical analysis title	Pruritus NRS
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.16495
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	20.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	51.4

Secondary: Percentage of participants from those with a Pruritus NRS of ≥5-points

at baseline re-randomized having achieved ≥4-point reduction from baseline at Week 16 who continue to exhibit ≥4-point reduction from baseline at Week 52

End point title	Percentage of participants from those with a Pruritus NRS of ≥5-points at baseline re-randomized having achieved ≥4-point reduction from baseline at Week 16 who continue to exhibit ≥4-point reduction from baseline at Week 52

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All participants who were randomized to Lebrikizumab 250 mg Q2W at Baseline Visit and re-randomized to Lebrikizumab 250 mg Q2W, Lebrikizumab 250 mg Q4W or placebo at Week 16 and received at least 1 dose of study treatment during the maintenance period and had evaluable data at week 52.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	34	22	
Units: percentage of partcipants				
number (confidence interval 95%)	67.6 (38.6 to 96.7)	87.4 (75.8 to 99.0)	94.4 (83.6 to 105.1)	

Statistical analyses

Statistical analysis title	Pruritus NRS
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.179704
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	19.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	51.2

Statistical analysis title	Pruritus NRS
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.08308
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	55.1

Secondary: Percentage change in SCORAD (From Those Re-randomized Having Achieved EASI-75 at Week 16) from baseline at Week 52

End point title	Percentage change in SCORAD (From Those Re-randomized Having Achieved EASI-75 at Week 16) from baseline at Week 52

End point description:

SCORAD assesses the extent and intensity of AD, it consists of 3 components: A=extent of AD as percentage of each defined body area and reported as sum of all areas, with maximum score of 100%. B=severity of 6 symptoms of AD (redness, swelling, oozing/crusting, excoriation, skin thickening/lichenification, dryness) assessed using following scale: none=0, mild=1, moderate=2, or severe=3 for maximum of 18 total points. C=subjective assessment of itch and sleeplessness recorded by participant on VAS, where 0=no itch/no sleeplessness and 10=worst imaginable itch/sleeplessness with maximum score of 20. SCORAD total score is calculated: A/5+7*B/2+ C to give total score range of 0 to 103, where 0=no disease to 103=severe disease. All participants who were randomized to Lebrikizumab 250 mg Q2W at Baseline Visit, re-randomized to Lebrikizumab 250 mg Q2W, Lebrikizumab 250 mg Q4W or placebo at Week 16 and received at least 1 dose of study treatment during maintenance period, had data at week 52.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	27	53	51	
Units: percent change				
least squares mean (standard error)	-67.60 (± 3.767)	-73.89 (± 2.718)	-73.85 (± 2.764)	

Statistical analyses

Statistical analysis title	SCORing Atopic Dermatitis (SCORAD)
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance

	- Lebrikizumab Responder/Lebrikizumab 250 Q4W
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.176748
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-6.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.46
upper limit	2.87

Statistical analysis title	SCORing Atopic Dermatitis (SCORAD)
Comparison groups	Maintenance - Lebrikizumab Responder/Placebo v Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.183151
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-6.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.48
upper limit	2.99

Secondary: Change From Baseline in European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) at Week 16 - Health State Index

End point title	Change From Baseline in European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) at Week 16 - Health State Index

End point description:

The European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) is a is a 2-part questionnaire which measure health status of the participant. The first component (Health state) is a descriptive system of the respondent's health comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using the United Kingdom (UK) algorithm, with scores ranging from -0.594 to 1, and the United States (US) algorithm, with scores ranging from -0.109 to 1. A higher score indicates better health state. All randomized participants, with non-missing EQ-5D-5L-Health State Index data at baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	281		
Units: score on a scale				
least squares mean (standard error)				
Health State Index UK	0.0 (± 0.02)	0.1 (± 0.02)		
Health State Index US	0.0 (± 0.01)	0.1 (± 0.01)		

Statistical analyses

Statistical analysis title	EQ-5D-5L
Statistical analysis description: UK	
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.1

Notes:
[1] - UK

Statistical analysis title	EQ-5D-5L
Statistical analysis description: US	
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.000001
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.1

Notes:

[2] - US

Secondary: Change From Baseline in EQ-5D-5L at Week 16 - Visual Analog Scale (VAS)

End point title	Change From Baseline in EQ-5D-5L at Week 16 - Visual Analog Scale (VAS)

End point description:

The EQ-5D-5L is a 2-part measurement. The second part is assessed using a VAS that ranged from 0 to 100 millimeter (mm), where 0 is the worst health you can imagine and 100 is the best health you can imagine. LS Mean was calculated using the ANCOVA model with treatment and stratification factors of geographic region, age group, baseline IGA (3 versus 4) score as fixed factors and baseline value as covariate. All randomized participants, with non-missing EQ-5D-5L-VAS data at baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	277		
Units: millimeters (mm)				
least squares mean (standard error)	5.2 (± 1.62)	9.7 (± 1.36)		

Statistical analyses

Statistical analysis title	EQ-5D-5L-VAS
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	422
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005304
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	7.6

Secondary: Change from Baseline in Patient Oriented Eczema Measure (POEM) at Week 16

End point title	Change from Baseline in Patient Oriented Eczema Measure (POEM) at Week 16

End point description:

POEM is a 7-item, validated, questionnaire used by the participant to assess disease symptoms over the last week. The participant is asked to respond to 7 questions on skin dryness, itching, flaking, cracking, sleep loss, bleeding and weeping. All 7 answers carry equal weight with a total possible score from 0 to 28 (answers scored as: No days=0; 1-2 days = 1; 3-4 days = 2; 5-6 days = 3; everyday = 4). A high score is indicative of a poor quality of life. POEM responses will be captured using an electronic diary and transferred into the clinical database. All randomized participants, with observed POEM data, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MMRM was used to handle all missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	184		
Units: score on a scale				
least squares mean (standard error)	-3.5 (± 0.77)	-9.5 (± 0.52)		

Statistical analyses

Statistical analysis title	Patient Oriented Eczema Measure (POEM)
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	249
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.000001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.7
upper limit	-4.3

Secondary: Change from Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety at Week 16-Adolescents

End point title	Change from Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety at Week 16-Adolescents

End point description:

PROMIS® is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. Participants ≤17 years will complete pediatric versions for the duration of the study. PROMIS anxiety has 8 questions on Emotion Distress-Anxiety (or Pediatric Anxiety Symptom). Each question has 5 response options with values from 1 to 5. Total raw scores were converted to T-Scores (mean = 50 and a standard deviation = 10) with higher scores representing greater anxiety. All randomized, adolescent participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	30		
Units: T-score				
least squares mean (standard error)	0.12 (± 2.129)	-2.79 (± 1.550)		

Statistical analyses

Statistical analysis title	PROMIS
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.241275
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.85
upper limit	2.03

Secondary: Change From Baseline in PROMIS Anxiety at Week 16 - Adults

End point title	Change From Baseline in PROMIS Anxiety at Week 16 - Adults

End point description:

PROMIS® is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. Participants ≤17 years will complete pediatric versions for the duration of the study. PROMIS anxiety has 8 questions on Emotion Distress-Anxiety (or Pediatric Anxiety Symptom). Each question has 5 response options with values from 1 to 5. Total raw scores were converted to T-Scores (mean = 50 and a standard deviation = 10) with higher scores representing greater anxiety. All randomized, adults participants, with Week 16 PROMIS anxiety data, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing Values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	246		
Units: T-score				
least squares mean (standard error)	-0.45 (± 0.580)	-3.18 (± 0.422)		

Statistical analyses

Statistical analysis title	PROMIS
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000116
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-2.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.12
upper limit	-1.36

Secondary: Change from Baseline in PROMIS Depression at Week 16- Adolescents

End point title	Change from Baseline in PROMIS Depression at Week 16-Adolescents

End point description:

PROMIS® is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. Participants ≤17 years will complete pediatric versions for the duration of the study. PROMIS anxiety has 8 questions on Emotion Distress-Anxiety (or Pediatric Anxiety Symptom). Each question has 5 response options with values from 1 to 5. Total raw scores were

converted to T-Scores (mean = 50 and a standard deviation = 10) with higher scores representing greater anxiety. All randomized, adolescent participants, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	30		
Units: T-score				
least squares mean (standard error)	-0.57 (± 2.047)	-1.67 (± 1.493)		

Statistical analyses

Statistical analysis title	PROMIS Depression
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.645132
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.86
upper limit	3.67

Secondary: Change From Baseline in PROMIS Depression at Week 16- Adults

End point title	Change From Baseline in PROMIS Depression at Week 16-Adults

End point description:

PROMIS® is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. Participants ≤17 years will complete pediatric versions for the duration of the study. PROMIS anxiety has 8 questions on Emotion Distress-Anxiety (or Pediatric Anxiety Symptom). Each question has 5 response options with values from 1 to 5. Total raw scores were converted to T-Scores (mean = 50 and a standard deviation = 10) with higher scores representing greater anxiety. All randomized, adult participants, with Week 16 PROMIS Depression data, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	246		
Units: T-score				
least squares mean (standard error)	0.16 (± 0.540)	-2.59 (± 0.392)		

Statistical analyses

Statistical analysis title	PROMIS Depression
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000031
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-2.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.03
upper limit	-1.47

Secondary: Change from Baseline in Asthma Control Questionnaire (ACQ-5) score at Week 16 in participants who have self-reported comorbid asthma

End point title	Change from Baseline in Asthma Control Questionnaire (ACQ-5) score at Week 16 in participants who have self-reported comorbid asthma

End point description:

The ACQ-5 is a five-item, self-completed questionnaire, which is used as a measure of asthma control of a participant. The five questions (concerning nocturnal awakening, waking in the morning, activity limitation, shortness of breath and wheeze) enquire about the frequency and/or severity of symptoms over the previous week. The response options for all these questions range from zero (no impairment/limitation) to six (total impairment/ limitation) scale. The ACQ-5 score is the average of the individual item scores and ranges from 0 (totally controlled) to 6 (severely uncontrolled). Higher scores indicate lower asthma control. All randomized participants, with non-missing baseline ACQ-5 score, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. Missing values were imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	75		
Units: score on a scale				
least squares mean (standard error)	0.19 (± 0.140)	0.19 (± 0.108)		

Statistical analyses

Statistical analysis title	Asthma Control Questionnaire (ACQ-5) Score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.974417
Method	ANCOVA
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.26

Secondary: Change from Baseline in Children's Dermatology Life Quality Index (CDLQI) at Week 16

End point title	Change from Baseline in Children's Dermatology Life Quality Index (CDLQI) at Week 16

End point description:

The CDLQI questionnaire is designed for use in children (4 to 16 years of age). It consists of 10 items that are grouped into 6 domains: symptoms & feelings, leisure, school or holidays, personal relationships, sleep, & treatment. The scoring of each question is: Very much =3; Quite a lot = 2; Only a little = 1; Not at all = 0. CDLQI total score is calculated by summing all 10 items responses and has a range of 0 to 30 (higher scores are indicative of greater impairment). All randomized, adolescent participants, with non-missing baseline CDLQI score, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MMRM was used to handle all missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	17		
Units: score on a scale				
least squares mean (standard error)	-3.4 (± 2.10)	-7.6 (± 1.13)		

Statistical analyses

Statistical analysis title	CDLQI
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.084769
Method	Mixed models analysis
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	0.6

Secondary: Percentage of Participants With a Pruritus NRS Score of ≥5 Points at Baseline Who Achieve a ≥4-point Reduction From Baseline to Week 4

End point title	Percentage of Participants With a Pruritus NRS Score of ≥5 Points at Baseline Who Achieve a ≥4-point Reduction From Baseline to Week 4

End point description:

Pruritus NRS is an 11-point scale used by participants to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". All randomized participants, with a Pruritus NRS Score of ≥5 Points at Baseline, even if the participant does not take the assigned treatment, does not receive the correct treatment, or otherwise does not follow the protocol. One investigational site with eighteen participants was excluded from analysis due to GCP issues. MCMC-MI was used to handle missing data.

End point type	Secondary

End point timeframe:

Baseline to Week 4

End point values	Induction - Placebo	Induction - Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	234		
Units: percentage of participants				
number (confidence interval 95%)	3.3 (0.1 to 6.6)	18.1 (13.2 to 23.1)		

Statistical analyses

Statistical analysis title	Pruritus NRS score
Comparison groups	Induction - Placebo v Induction - Lebrikizumab Q2W
Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000252
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.2
upper limit	20.1

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 52

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug. Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Maintenance - Lebrikizumab Responder/Placebo

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50. Two placebo SC injections as loading dose on Week 16 and Week 18.

Reporting group title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50. To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. Two placebo injections on Week 18.

Reporting group title	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W

Reporting group description:

Maintenance Primary Population: Maintenance Period (Week 16 to Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. To maintain the blind, for participants who received Lebrikizumab in the Induction Period, the maintenance loading dose is: One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18.

Reporting group title	Induction - Lebrikizumab Q2W

Reporting group description:

Induction Period (Baseline-Week 16): 500 milligram (mg) Lebrikizumab (2 x 250 mg) SC injections as a loading dose at Baseline and Week 2 visits followed by a single 250 mg Lebrikizumab injection Q2W from Week 4 until Week 14.

Reporting group title	Maintenance - Placebo Responder/ Placebo

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16 to Week 52): One SC injection of Placebo Q2W until Week 50. Two placebo SC injections as loading dose on Week 16 and Week 18.

Reporting group title	Induction - Placebo

Reporting group description:

Induction Period (Baseline-Week 16): Two subcutaneous (SC) injections of Placebo as a loading dose at Baseline and Week 2 followed by a single injection every 2 weeks (Q2W) from Week 4 until Week 14.

Reporting group title	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection Q2W until Week 50. For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18.

Reporting group title	Escape Arm Wk 16 - Maintenance OL- PBO/Leb 250 Q2W

Reporting group description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50

in an open-label fashion. For participants who received placebo in the Induction Period, the loading dose is: Two 250 mg Lebrikizumab SC injection on Week 16. Two 250 mg Lebrikizumab SC injections on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Reporting group title	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W

Reporting group description:

Maintenance Escape Period (Week 16 to Week 52): Blinded loading doses based on prior treatment assignment will be administered, followed by one 250 mg Lebrikizumab SC injection Q2W until Week 50 in an open-label fashion. To maintain the loading dose blind, for participants who received Lebrikizumab in the Induction Period, the loading dose is: One 250 mg Lebrikizumab SC injection and one placebo on Week16. One 250 mg Lebrikizumab SC injection and one placebo SC injection on Week 18. For participants who do not maintain an acceptable response during the Maintenance Period and entered the Escape Arm, the loading doses will be administrated at entry and 2 weeks after entry based on the treatment assignment prior to entering escape arm. Participants who did not achieve an EASI-50 response after 8 weeks in the Escape Arm were terminated from the study.

Reporting group title	Escape Arm Wk 24-48 - Maintenance OL - Leb 250 Q2W

Reporting group description:

Escape Arm Week 24 to 48 - Maintenance Open Label Lebrikizumab 250 Q2W.

Reporting group title	Maintenance - Placebo Responder/Lebrikizumab Q4W

Reporting group description:

Maintenance Secondary Population: Maintenance Period (Week 16-Week 52): One 250 mg Lebrikizumab SC injection every 4 weeks (Q4W) on Weeks 20, 24, 28, 32, 36, 40, 44, and 48. One placebo SC injection Q4W on Weeks 22, 26, 30, 34, 38, 42, 46, and 50. For participants who received placebo in the Induction Period, the maintenance loading dose is: Two 250 mg Lebrikizumab SC injections on Week 16. Two placebo injections on Week 18.

Serious adverse events	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	2 / 59 (3.39%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
metastases to bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
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			
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paternal exposure during pregnancy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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			
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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			
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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			
pancreatitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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			
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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			
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
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 - Lebrikizumab Q2W	Maintenance - Placebo Responder/ Placebo	Induction - Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	4 / 149 (2.68%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
metastases to bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastases to liver			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[1]	0 / 147 (0.00%)	0 / 3 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (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
paternal exposure during pregnancy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (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
myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
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			
pancreatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
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			
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
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 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine infection			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (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

Serious adverse events	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W	Escape Arm Wk 16 - Maintenance OL-PBO/Leb 250 Q2W	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	5 / 125 (4.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
metastases to bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
metastases to liver			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paternal exposure during pregnancy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
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			
cardiac failure			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
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			
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (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			
pancreatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
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	Escape Arm Wk 24-	Maintenance -	

	48 - Maintenance OL - Leb 250 Q2W	Placebo Responder/Lebrikizumab Q4W	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	2 / 9 (22.22%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
metastases to bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to liver			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
humerus fracture			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple injuries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
paternal exposure during pregnancy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ulna fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
pancreatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Maintenance - Lebrikizumab Responder/Placebo	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q4W	Maintenance - Lebrikizumab Responder/Lebrikizumab 250 Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 30 (50.00%)	32 / 59 (54.24%)	36 / 59 (61.02%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
bowen's disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
fibroadenoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
aortic arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
haematoma			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cyst rupture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

injection site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injection site urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
swelling			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vaccination site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	2 / 59 (3.39%)	2 / 59 (3.39%)
occurrences (all)	0	3	2
vaccination site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	2 / 59 (3.39%)	1 / 59 (1.69%)
occurrences (all)	0	2	1
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sarcoidosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 15 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	3	0
bartholin's cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
breast hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
breast ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 15 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
penis disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[7]	0 / 15 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 15 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
vulvovaginal dryness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
allergic sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
haemoptysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
nasal septum deviation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

upper respiratory tract inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 30 (6.67%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	2	1	0
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
middle insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sleep disorder due to general medical condition, insomnia type			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood bicarbonate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood glucose decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
blood phosphorus increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
blood alkaline phosphatase increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase abnormal alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood testosterone decreased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
blood pressure increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
blood pressure diastolic increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
electrocardiogram abnormal alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

eosinophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
lymphocyte percentage decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
mean cell haemoglobin concentration decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
mean cell volume increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[10]	0 / 15 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
urine ketone body present			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
animal bite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
bone contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
corneal abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0

fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
lip injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
muscle strain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
neck injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
procedural headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
post procedural complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
procedural pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	2
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
skin laceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
stress fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1

thermal burn			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 30 (6.67%)	2 / 59 (3.39%)	4 / 59 (6.78%)
occurrences (all)	2	2	7
wound dehiscence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	3 / 59 (5.08%)	2 / 59 (3.39%)
occurrences (all)	2	3	2
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
narcolepsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
eosinophilia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypochromic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
lymphocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
auricular pseudocyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
paraesthesia ear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
atopic keratoconjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cataract			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	4 / 59 (6.78%)	1 / 59 (1.69%)
occurrences (all)	1	6	1
dark circles under eyes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
epiretinal membrane			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
episcleritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eye discharge			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
eye swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eyelid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eyelid erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

vision blurred			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
angular cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
breath odour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
epiploic appendagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
gastrointestinal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
haematemesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	2	0
hiatus hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
oral mucosal eruption			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
peptic ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	2 / 59 (3.39%)	1 / 59 (1.69%)
occurrences (all)	1	2	1
angioedema			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 30 (10.00%)	3 / 59 (5.08%)	3 / 59 (5.08%)
occurrences (all)	3	3	3
diffuse alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

drug eruption			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
hair disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
pityriasis rosea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
prurigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
rash erythematous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
skin lesion inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
urticaria papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Renal and urinary disorders			

acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
bladder disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypertonic bladder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
renal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	2 / 59 (3.39%)
occurrences (all)	0	1	2
bursitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
coccydynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
osteitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	3 / 59 (5.08%)	1 / 59 (1.69%)
occurrences (all)	1	3	1
cellulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 30 (6.67%)	5 / 59 (8.47%)	0 / 59 (0.00%)
occurrences (all)	3	6	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
demodicidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	2
dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0

dermatitis infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eczema impetiginous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
eczema infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	3 / 59 (5.08%)	3 / 59 (5.08%)
occurrences (all)	0	3	3
fungal skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
genital herpes simplex			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
herpes dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	2 / 59 (3.39%)	1 / 59 (1.69%)
occurrences (all)	0	2	1
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0

molluscum contagiosum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	3 / 59 (5.08%)	3 / 59 (5.08%)
occurrences (all)	2	3	5
ophthalmic herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	2 / 59 (3.39%)	0 / 59 (0.00%)
occurrences (all)	1	2	0
oral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
perineal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	2 / 59 (3.39%)	0 / 59 (0.00%)
occurrences (all)	0	2	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 30 (3.33%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
superinfection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

superinfection bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tinea barbae			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
tinea capitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
tinea cruris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
tinea versicolour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	3 / 59 (5.08%)	3 / 59 (5.08%)
occurrences (all)	0	4	5
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 15 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Induction - Lebrikizumab Q2W	Maintenance - Placebo Responder/ Placebo	Induction - Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	157 / 295 (53.22%)	3 / 5 (60.00%)	97 / 149 (65.10%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
bowen's disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
fibroadenoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
ovarian germ cell teratoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 147 (0.00%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
Vascular disorders			
aortic arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
hot flush			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	2	0	2
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
cyst rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	3	0	2
injection site erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
injection site discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
injection site haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	3	0	1
injection site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	4	0	0
injection site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1

injection site urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	2
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
vaccination site pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
vaccination site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
food allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
sarcoidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 147 (0.00%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
bartholin's cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 147 (0.00%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
breast hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
breast ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 147 (0.00%)	0 / 3 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 147 (0.00%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
penis disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 148 (0.00%)	0 / 2 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[8]	0 / 147 (0.00%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	1 / 147 (0.68%)	0 / 3 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
allergic sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
haemoptysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
nasal polyps			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	2	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 295 (1.36%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	0	0	3
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	2
middle insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
sleep disorder due to general medical condition, insomnia type			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood bicarbonate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood glucose decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood phosphorus increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
blood alkaline phosphatase abnormal alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
blood uric acid increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood testosterone decreased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
blood pressure increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
blood pressure diastolic increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
electrocardiogram abnormal alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
eosinophil count increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0

gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
lymphocyte percentage decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
mean cell haemoglobin concentration decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
mean cell volume increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
neutrophil count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
platelet count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	1	0	2
prostatic specific antigen increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[10]	0 / 148 (0.00%)	0 / 2 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
urine ketone body present			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
animal bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
arthropod bite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
bone contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
corneal abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
face injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
injury corneal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
lip injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
neck injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	1 / 5 (20.00%)	0 / 149 (0.00%)
occurrences (all)	0	1	0
overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
procedural headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
post procedural complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
procedural pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	0	0	2
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
skin laceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
stress fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
wound dehiscence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 295 (1.36%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	4	0	0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	15 / 295 (5.08%)	1 / 5 (20.00%)	8 / 149 (5.37%)
occurrences (all)	17	1	8
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	1	0	2
narcolepsy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
hypochromic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
lymphocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auricular pseudocyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
paraesthesia ear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
atopic keratoconjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	3	0	1
cataract			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	1	0	2
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 295 (2.37%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	7	0	2
dark circles under eyes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 295 (2.37%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	8	0	0
epiretinal membrane			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
episcleritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
eye discharge			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

eye swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
eyelid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
eyelid erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	0	0	2
keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
keratoconus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
angular cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
breath odour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
dental caries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	2	0	1
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
epiploic appendagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
gastrointestinal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
haematemesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
haemorrhoids			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
hiatus hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
inguinal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 295 (1.36%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
oral mucosal eruption			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
peptic ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	1	0	3
angioedema			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	2	0	1
dermatitis psoriasiform			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	1	0	2
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	27 / 295 (9.15%)	0 / 5 (0.00%)	38 / 149 (25.50%)
occurrences (all)	31	0	41
diffuse alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

drug eruption			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
hair disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
purpura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 295 (1.69%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	5	0	1
prurigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
rash erythematous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	2
rash papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
skin fissures			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
skin disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
skin lesion inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
urticaria papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	3	0	1
Renal and urinary disorders			

acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
bladder disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
hypertonic bladder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
pollakiuria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
renal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Endocrine disorders			
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	3	0	1
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
coccydynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
osteitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	1 / 5 (20.00%)	1 / 149 (0.67%)
occurrences (all)	1	1	2
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	2	0	2
cellulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	21 / 295 (7.12%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	22	0	3
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
demodicidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	2	0	1
dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

dermatitis infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
eczema herpeticum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
eczema impetiginous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
eczema infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
folliculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	1	0	3
fungal skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 295 (1.02%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
genital herpes simplex			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
herpes dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	1	0	2
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	0	0	3
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

molluscum contagiosum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	15 / 295 (5.08%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	17	0	3
ophthalmic herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 295 (1.36%)	0 / 5 (0.00%)	3 / 149 (2.01%)
occurrences (all)	4	0	3
oral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
paronychia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 295 (0.68%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
perineal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
pharyngotonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	2	0	1
superinfection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
subcutaneous abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0

superinfection bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tinea barbae			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tinea capitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
tinea infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
tinea pedis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
tinea versicolour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
tooth abscess alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
tooth infection alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
upper respiratory tract infection alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	2 / 149 (1.34%)
occurrences (all)	0	0	2
urinary tract infection alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 295 (1.69%)	1 / 5 (20.00%)	1 / 149 (0.67%)
occurrences (all)	5	1	1
viral infection alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
vulvovaginal candidiasis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 147 (0.00%)	0 / 3 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
decreased appetite alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
glucose tolerance impaired alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 295 (0.00%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 295 (0.34%)	0 / 5 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Maintenance - Placebo Responder/Lebrikizumab 250 Q2W	Escape Arm Wk 16 - Maintenance OL-PBO/Leb 250 Q2W	Escape Arm Wk 16 - Maintenance OL - Leb NR/Leb 250 Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 11 (72.73%)	68 / 108 (62.96%)	77 / 125 (61.60%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
bowen's disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	3
fibroadenoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 6 (0.00%)	1 / 54 (1.85%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
aortic arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	3 / 125 (2.40%)
occurrences (all)	0	0	3
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
thrombophlebitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
cyst rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	3 / 125 (2.40%)
occurrences (all)	0	0	3
injection site erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
injection site haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
injection site pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
injection site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
injection site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1

injection site urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vaccination site pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
vaccination site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
sarcoidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
seasonal allergy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
bartholin's cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 6 (0.00%)	1 / 54 (1.85%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
breast hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
breast ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
penis disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 5 (0.00%)	0 / 54 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[8]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
allergic sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
haemoptysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
nasal polyps			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	2 / 125 (1.60%)
occurrences (all)	0	1	2
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
throat tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
middle insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
panic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
sleep disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
sleep disorder due to general medical condition, insomnia type			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
blood bicarbonate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
blood lactate dehydrogenase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
blood glucose decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blood phosphorus increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
blood alkaline phosphatase abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blood testosterone decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
blood pressure diastolic increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
electrocardiogram abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
eosinophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0

gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
lymphocyte percentage decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
mean cell haemoglobin concentration decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
mean cell volume increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
neutrophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[10]	0 / 5 (0.00%)	1 / 54 (1.85%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
urine ketone body present			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
animal bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
bone contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
corneal abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
lip injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
neck injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
procedural headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
post procedural complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
skin laceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
stress fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	2 / 108 (1.85%)	2 / 125 (1.60%)
occurrences (all)	1	3	2
wound dehiscence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	2 / 108 (1.85%)	0 / 125 (0.00%)
occurrences (all)	1	2	0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	3 / 108 (2.78%)	1 / 125 (0.80%)
occurrences (all)	0	3	1
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
narcolepsy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
eosinophilia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
hypochromic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
lymphocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auricular pseudocyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
paraesthesia ear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
Eye disorders			
atopic keratoconjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
cataract			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	12 / 108 (11.11%)	1 / 125 (0.80%)
occurrences (all)	1	14	1
dark circles under eyes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	3 / 108 (2.78%)	1 / 125 (0.80%)
occurrences (all)	0	3	1
epiretinal membrane			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
episcleritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eye discharge			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
eye pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	2 / 108 (1.85%)	1 / 125 (0.80%)
occurrences (all)	1	2	1

eye swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
eyelid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eyelid erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
keratoconus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
lacrimation increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
vision blurred			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
vitreous floaters			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	0 / 125 (0.00%)
occurrences (all)	0	3	0
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
angular cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
breath odour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	1 / 125 (0.80%)
occurrences (all)	0	2	1
dental caries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
epiploic appendagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
food poisoning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
gastrointestinal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
gastrointestinal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
haematemesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
hiatus hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
oral mucosal eruption			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
peptic ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	3 / 108 (2.78%)	2 / 125 (1.60%)
occurrences (all)	1	3	2
angioedema			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	3 / 108 (2.78%)	6 / 125 (4.80%)
occurrences (all)	0	3	8
diffuse alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

drug eruption			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
dyshidrotic eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
hair disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
intertrigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
prurigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
rash erythematous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
seborrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
skin lesion inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
urticaria papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			

acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
bladder disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hypertonic bladder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
renal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	3 / 108 (2.78%)	0 / 125 (0.00%)
occurrences (all)	0	3	0
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	2 / 125 (1.60%)
occurrences (all)	0	1	3
bursitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
coccydynia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
osteitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	6 / 108 (5.56%)	2 / 125 (1.60%)
occurrences (all)	0	7	2
cellulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	5 / 108 (4.63%)	3 / 125 (2.40%)
occurrences (all)	0	5	3
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
demodicidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

dermatitis infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eczema impetiginous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
eczema infected			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	2 / 108 (1.85%)	3 / 125 (2.40%)
occurrences (all)	1	2	3
fungal skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
genital herpes simplex			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
herpes dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	2 / 125 (1.60%)
occurrences (all)	0	1	3
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	3	0
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

molluscum contagiosum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 11 (18.18%)	6 / 108 (5.56%)	10 / 125 (8.00%)
occurrences (all)	2	10	14
ophthalmic herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	4 / 108 (3.70%)	3 / 125 (2.40%)
occurrences (all)	0	7	4
oral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
perineal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
pharyngitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
superinfection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

superinfection bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
tinea barbae			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tinea capitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
tinea versicolour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	4 / 108 (3.70%)	2 / 125 (1.60%)
occurrences (all)	0	4	2
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	2 / 108 (1.85%)	3 / 125 (2.40%)
occurrences (all)	0	5	3
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 6 (0.00%)	0 / 54 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 11 (18.18%)	1 / 108 (0.93%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
obesity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 108 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Escape Arm Wk 24-48 - Maintenance OL - Leb 250 Q2W	Maintenance - Placebo Responder/Lebrikizumab Q4W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 11 (45.45%)	4 / 9 (44.44%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
bowen's disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
fibroadenoma of breast			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
ovarian germ cell teratoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
aortic arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hot flush			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
thrombophlebitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cyst rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
fatigue				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
injection site erythema				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site discomfort				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site haematoma				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site pruritus				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site reaction				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injection site swelling				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

injection site urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vaccination site pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vaccination site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
food allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
sarcoidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
seasonal allergy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
bartholin's cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
breast hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
breast ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
penis disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 8 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[8]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
vulvovaginal dryness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
allergic sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 11 (18.18%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
haemoptysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
nasal polyps			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
nasal septum deviation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
oropharyngeal pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
rhinitis allergic				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
rhinorrhoea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
sinus congestion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
sleep apnoea syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
throat tightness				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
upper respiratory tract inflammation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
middle insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
panic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
restlessness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
sleep disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
sleep disorder due to general medical condition, insomnia type				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
Investigations				
alanine aminotransferase increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
blood bicarbonate decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
blood lactate dehydrogenase increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
blood glucose decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
blood cholesterol increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
blood phosphorus increased				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blood alkaline phosphatase abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
blood testosterone decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blood pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blood pressure diastolic increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
electrocardiogram abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
eosinophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	

gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
hepatic enzyme increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
lymphocyte percentage decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
mean cell haemoglobin concentration decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
mean cell volume increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
neutrophil count increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
neutrophil count decreased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
platelet count increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
prostatic specific antigen increased				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed[10]	0 / 8 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
urine ketone body present			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
animal bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
arthropod bite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
bone contusion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
concussion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
clavicle fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
corneal abrasion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
contusion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
epicondylitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
face injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
fall				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

fibula fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
hand fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
injury corneal				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
joint dislocation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
ligament sprain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
limb injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
lip injury				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
muscle strain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
neck injury				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
overdose				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
procedural headache				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
post procedural complication				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
procedural pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
skin abrasion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
skin laceration				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
stress fracture				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
thermal burn				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tibia fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	
occurrences (all)	1	0	
wound dehiscence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tachycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cerebellar syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
narcolepsy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
presyncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
eosinophilia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypochromic anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
lymphocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
auricular pseudocyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
paraesthesia ear			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
atopic keratoconjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cataract			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dark circles under eyes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
epiretinal membrane			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
episcleritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
eye discharge			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
eye pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	

eye swelling				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eyelid cyst				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eyelid erosion				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
keratitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
keratoconus				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
lacrimation increased				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
ocular hyperaemia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
retinopathy				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
vision blurred				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vitreous floaters			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
angular cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
breath odour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
constipation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
dental caries				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	2		
diarrhoea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
dyspepsia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
epiploic appendagitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
flatulence				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
gastritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
food poisoning				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
gastrointestinal disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
gastrointestinal inflammation				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
haematemesis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
haemorrhoids				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
hiatus hernia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
inguinal hernia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
irritable bowel syndrome				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)		
occurrences (all)	1	0		
nausea				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
oral mucosal eruption				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
peptic ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	
occurrences (all)	1	0	
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
angioedema			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatitis psoriasiform			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatitis atopic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 11 (18.18%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
diffuse alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	

drug eruption				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
dyshidrotic eczema				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eczema				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
erythema				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
hair disorder				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
hyperhidrosis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
intertrigo				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
night sweats				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
photosensitivity reaction				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
pityriasis rosea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
purpura			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
prurigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
rash erythematous			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
rash papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	

rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
seborrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
skin fissures			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	
occurrences (all)	1	0	
skin disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
skin lesion inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
urticaria papular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			

acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
bladder disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
bladder irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
hypertonic bladder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
pollakiuria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
renal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
renal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
bursitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
coccydynia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
costochondritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
flank pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)		
occurrences (all)	0	1		
joint swelling				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
muscle spasms				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
musculoskeletal pain				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
myalgia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)		
occurrences (all)	1	0		
osteitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cellulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
demodicidosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	

dermatitis infected				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eczema herpeticum				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eczema impetiginous				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
eczema infected				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
erysipelas				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
folliculitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
fungal skin infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
gastroenteritis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
genital herpes simplex				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
herpes dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	
occurrences (all)	1	0	
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
large intestine infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	

molluscum contagiosum				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
nasopharyngitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 11 (9.09%)	1 / 9 (11.11%)		
occurrences (all)	1	1		
ophthalmic herpes zoster				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
oral herpes				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)		
occurrences (all)	1	0		
oral infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
otitis externa				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
paronychia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
perineal abscess				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
pharyngitis				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
pneumonia				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
pharyngitis streptococcal				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
pharyngotonsillitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
post procedural infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
rhinitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
skin infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
superinfection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
subcutaneous abscess				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		

superinfection bacterial				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea barbae				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea capitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea cruris				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea infection				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea pedis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tinea versicolour				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tonsillitis				
alternative dictionary used: MedDRA 24.1				
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)		
occurrences (all)	0	0		
tonsillitis bacterial				
alternative dictionary used: MedDRA 24.1				

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	
occurrences (all)	1	0	
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
glucose tolerance impaired			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypoglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	
obesity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	
occurrences (all)	0	0	

Notes:

[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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[10] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[11] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 May 2020	Revised to align with FDA and EU received recommendations and regulations, to add more clarifications and ensuring consistencies between different sections, and to be consistent across the Phase 3 studies of Lebrikizumab in atopic dermatitis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

One investigational site with eighteen participants was excluded from analysis due to GCP issues.

Notes: