



Clinical trial results:

A LONG-TERM STUDY TO ASSESS THE SAFETY AND EFFICACY OF LEBRIKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS (ADJOIN)

Summary

EudraCT number	2020-001211-24
Trial protocol	PL DE LV LT EE FR BG ES
Global end of trial date	22 April 2025

Results information

Result version number	v1
This version publication date	03 August 2025
First version publication date	03 August 2025

Trial information

Trial identification

Sponsor protocol code	DRM06-AD07/J2T-DM-KGAA
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04392154
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 119866, Eli Lilly trial alias: J2T-DM-KGAA, Trial Number: 17789

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	1 Lilly Corporate Center, Indianapolis, United States, 46285-0001
Public contact	Clinical Trial Registry Office, Eli Lilly and Company, 1 317650 421 7200, EU_Lilly_Clinical_Trials@lilly.com
Scientific contact	Clinical Trial Registry Office, Eli Lilly and Company, 1 317650 421 7200, EU_Lilly_Clinical_Trials@lilly.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-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	Interim
Date of interim/final analysis	19 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 July 2024
Global end of trial reached?	Yes
Global end of trial date	22 April 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to assess the long-term safety and efficacy of lebrikizumab in patients with moderate-to-severe AD.

This is designed to assess the long-term safety and efficacy of lebrikizumab for moderate-to-severe atopic dermatitis. It will last up to 33 months.

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	15 June 2020
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	Singapore: 8
Country: Number of subjects enrolled	United States: 663
Country: Number of subjects enrolled	Ukraine: 9
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Canada: 94
Country: Number of subjects enrolled	Latvia: 8
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	Taiwan: 55
Country: Number of subjects enrolled	Poland: 158
Country: Number of subjects enrolled	Mexico: 4
Country: Number of subjects enrolled	Australia: 26
Country: Number of subjects enrolled	Bulgaria: 10
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Lithuania: 13
Country: Number of subjects enrolled	Germany: 62
Country: Number of subjects enrolled	Estonia: 5

Worldwide total number of subjects	1153
EEA total number of subjects	267

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	292
Adults (18-64 years)	799
From 65 to 84 years	50
85 years and over	12

Subject disposition

Recruitment

Recruitment details:

This study consists of 2 parts:

- 100-week primary treatment period where participants were assigned to either Lebrikizumab Q4W or Q2W treatment arms.
- 32-week open label extension addendum

Pre-assignment

Screening details:

Eligible participants from primary treatment period could enter the open-label extension addendum. The current results reported are for the primary completion date (i.e., up to Week 100). Data beyond week 100 (i.e., 32-week open-label extension addendum) will be reported at the time of final results reporting.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Lebrikizumab Q4W

Arm description:

250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab Q4W
Investigational medicinal product code	LY3650150
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.

Arm title	Lebrikizumab Q2W
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Arm description:

250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab Q2W
Investigational medicinal product code	LY3650150
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.

Number of subjects in period 1	Lebrikizumab Q4W	Lebrikizumab Q2W
Started	141	1012
Completed	103	675
Not completed	38	337
Site Closure	-	4
Consent withdrawn by subject	18	138
Physician decision	1	5
Adverse events	3	46
Geopolitical conflict	1	1
Pregnancy	1	8
Sponsor Decision	1	14
Lost to follow-up	11	61
Due to epidemic/pandemic	-	1
Protocol deviation	1	12
Lack of efficacy	1	47

Baseline characteristics

Reporting groups

Reporting group title	Lebrikizumab Q4W
Reporting group description: 250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.	
Reporting group title	Lebrikizumab Q2W
Reporting group description: 250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.	

Reporting group values	Lebrikizumab Q4W	Lebrikizumab Q2W	Total
Number of subjects	141	1012	1153
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	34.9 ± 16.96	32.5 ± 17.23	-
Gender categorical Units: Subjects			
Female	82	513	595
Male	59	499	558
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	16	17
Asian	21	199	220
Native Hawaiian or Other Pacific Islander	1	9	10
Black or African American	9	138	147
White	106	610	716
More than one race	3	25	28
Unknown or Not Reported	0	15	15
Region of Enrollment Units: Subjects			
Singapore	1	7	8
United States	72	591	663
Ukraine	5	4	9
Spain	0	7	7
Canada	14	80	94
Latvia	3	5	8
South Korea	2	25	27
Taiwan	4	51	55
Poland	23	135	158
Mexico	2	2	4
Australia	3	23	26
Bulgaria	0	10	10
France	1	3	4

Lithuania	1	12	13
Germany	10	52	62
Estonia	0	5	5

End points

End points reporting groups

Reporting group title	Lebrikizumab Q4W
Reporting group description: 250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.	
Reporting group title	Lebrikizumab Q2W
Reporting group description: 250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.	

Primary: Percentage of Participants Discontinued From Study Treatment Due to Adverse Events

End point title	Percentage of Participants Discontinued From Study Treatment Due to Adverse Events ^[1]
End point description: Percentage of participants discontinued from study treatment due to adverse events is reported. Analysis Population Description (APD): All participants who received at least one dose of study drug.	
End point type	Primary
End point timeframe: Baseline to Week 100	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As per planned analysis only descriptive data was planned to be analyzed and reported.

End point values	Lebrikizumab Q4W	Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	1012		
Units: Percentage of participants				
number (not applicable)	2.1	4.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of Investigator Global Assessment (IGA) Score 0 or 1 at Week 100

End point title	Percentage of Participants With a Response of Investigator Global Assessment (IGA) Score 0 or 1 at Week 100
End point description: The IGA measures the investigator's global assessment of the participant's overall severity of their Atopic Dermatitis. The IGA is comprised of a 5-point numeric scale ranging from 0 (clear skin) to 4 (severe disease) and a score is selected using descriptors that best describe the overall appearance of the lesions at a given time point. APD: All participants who received at least one dose of study drug.	
End point type	Secondary

End point timeframe:

Week 100

End point values	Lebrikizumab Q4W	Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	1012		
Units: Percentage of participants				
number (not applicable)	80.1	60.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Response of Eczema Area and Severity Index-75 (EASI-75) at Week 100

End point title	Percentage of Participants Achieving Response of Eczema Area and Severity Index-75 (EASI-75) at Week 100
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End point description:

EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs, by scoring the extent of disease (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 (erythema, edema/papulation, excoriation, and lichenification) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head and neck, trunk, upper limbs, and lower limbs). Half scores are allowed. The final EASI score will be obtained by weight-averaging these 4 scores and will range from 0 to 72. A higher score represents greater disease severity.

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

End point type	Secondary
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End point timeframe:

Week 100

End point values	Lebrikizumab Q4W	Lebrikizumab Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	1012		
Units: Percentage of participants				
number (not applicable)	90.4	79.4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 100 Weeks

Adverse event reporting additional description:

All 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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Lebrikizumab Q4W
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Reporting group description:

250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.

Reporting group title	Lebrikizumab Q2W
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Reporting group description:

250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.

Serious adverse events	Lebrikizumab Q4W	Lebrikizumab Q2W	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 141 (3.55%)	41 / 1012 (4.05%)	
number of deaths (all causes)	0	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[1]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive breast carcinoma			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuroendocrine tumour			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[2]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
prostate cancer			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[3]	0 / 59 (0.00%)	2 / 499 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
influenza like illness			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic shock			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
food allergy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleural effusion			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary mass			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression suicidal			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
blood potassium decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
accident			
alternative dictionary used:			

MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ankle fracture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip fracture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple injuries			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
splenic rupture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
radius fracture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subdural haematoma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cervical cord compression			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
seizure			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
cataract			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sudden visual loss			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
hiatus hernia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine polyp			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
small intestinal obstruction			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
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 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
stevens-johnson syndrome			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
rotator cuff syndrome			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
covid-19			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacteraemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subcutaneous abscess			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vulval abscess			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[4]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ketoacidosis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
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.

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

Justification: 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 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.

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

Justification: 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	Lebrikizumab Q4W	Lebrikizumab Q2W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 141 (63.12%)	635 / 1012 (62.75%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
basal cell carcinoma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
fibroadenoma of breast			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
lipoma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
melanocytic naevus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[5]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
pyogenic granuloma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
seborrhoeic keratosis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
skin papilloma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	
occurrences (all)	0	7	
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
deep vein thrombosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
essential hypertension		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
haematoma		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hypertension		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	15 / 1012 (1.48%)
occurrences (all)	0	15
orthostatic hypotension		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
raynaud's phenomenon		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
thrombosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
venous thrombosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

Pregnancy, puerperium and perinatal conditions anembryonic gestation alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) morning sickness alternative dictionary used: MedDRA 27.1 subjects affected / exposed ^[6] occurrences (all) uterine hypertonus alternative dictionary used: MedDRA 27.1 subjects affected / exposed ^[7] occurrences (all)	 0 / 141 (0.00%) 0 0 / 82 (0.00%) 0 0 / 82 (0.00%) 0	 1 / 1012 (0.10%) 1 1 / 513 (0.19%) 1 1 / 513 (0.19%) 1	
General disorders and administration site conditions asthenia alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) chest discomfort alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) chest pain alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) fatigue alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) general physical health deterioration alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	 1 / 141 (0.71%) 1 0 / 141 (0.00%) 0 0 / 141 (0.00%) 0 0 / 141 (0.00%) 0 0 / 141 (0.00%) 0	 0 / 1012 (0.00%) 0 1 / 1012 (0.10%) 3 3 / 1012 (0.30%) 3 8 / 1012 (0.79%) 9 1 / 1012 (0.10%) 1	

influenza like illness			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	3	
injection site bruising			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
injection site haematoma			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
injection site pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
injection site pruritus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
injection site rash			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
injection site reaction			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)	
occurrences (all)	2	32	
injection site swelling			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
malaise			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
non-cardiac chest pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
peripheral swelling		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
pyrexia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
swelling face		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
vaccination site pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	8 / 1012 (0.79%)
occurrences (all)	0	16
vaccination site reaction		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
vascular stent stenosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
allergy to arthropod bite			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
allergy to venom			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
anaphylactic reaction			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
dust allergy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
drug hypersensitivity			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
food allergy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	
occurrences (all)	0	6	
hypersensitivity			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	3	
multiple allergies			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
seasonal allergy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	9 / 1012 (0.89%)	
occurrences (all)	0	10	
Reproductive system and breast disorders			
abnormal uterine bleeding			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[8]	0 / 82 (0.00%)	2 / 513 (0.39%)	
occurrences (all)	0	2	
breast mass			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
dysmenorrhoea			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[9]	1 / 82 (1.22%)	2 / 513 (0.39%)	
occurrences (all)	1	25	
erectile dysfunction			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[10]	1 / 59 (1.69%)	0 / 499 (0.00%)	
occurrences (all)	1	0	
fibrocystic breast disease			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
heavy menstrual bleeding			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[11]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
menopausal symptoms			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed ^[12]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
menstruation irregular			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[13]	0 / 82 (0.00%)	3 / 513 (0.58%)	
occurrences (all)	0	3	
ovarian cyst			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[14]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
prostatitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[15]	0 / 59 (0.00%)	1 / 499 (0.20%)	
occurrences (all)	0	1	
testicular cyst			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[16]	0 / 59 (0.00%)	1 / 499 (0.20%)	
occurrences (all)	0	1	
vaginal discharge			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[17]	1 / 82 (1.22%)	0 / 513 (0.00%)	
occurrences (all)	1	0	
vaginal haemorrhage			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed ^[18]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
asthma			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)
occurrences (all)	1	5
bronchial hyperreactivity		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
bronchospasm		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	2
cough		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)
occurrences (all)	1	13
dyspnoea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
epistaxis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	6
hypoxia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
nasal congestion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
nasal polyps		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

nasal septum deviation			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
oropharyngeal pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	6 / 1012 (0.59%)	
occurrences (all)	1	6	
rhinitis allergic			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	
occurrences (all)	0	5	
rhinorrhoea			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	
occurrences (all)	0	7	
sinus congestion			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
sleep apnoea syndrome			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	
occurrences (all)	1	2	
tonsillar hypertrophy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Psychiatric disorders			

alcohol abuse		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
alcohol withdrawal syndrome		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
anxiety		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	11 / 1012 (1.09%)
occurrences (all)	1	11
apathy		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
attention deficit hyperactivity disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
autism spectrum disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
bipolar i disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
depression		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	10 / 1012 (0.99%)
occurrences (all)	0	10
insomnia		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	
occurrences (all)	1	7	
libido decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
major depression			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
mania			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
sleep disorder due to general medical condition, insomnia type			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	17 / 1012 (1.68%)	
occurrences (all)	0	18	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	
occurrences (all)	0	8	
blood cholesterol increased			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)
occurrences (all)	1	4
blood bicarbonate decreased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
blood creatinine increased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	2
bilirubin urine alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
bilirubin urine present alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
blood alkaline phosphatase increased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
blood creatine phosphokinase increased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
blood glucose decreased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
blood iron decreased alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

blood lactate dehydrogenase increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	3 / 1012 (0.30%) 3	
blood potassium increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	0 / 1012 (0.00%) 0	
blood pressure diastolic increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
blood pressure increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	3 / 1012 (0.30%) 3	
blood testosterone decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2	0 / 1012 (0.00%) 0	
blood uric acid increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	2 / 1012 (0.20%) 2	
blood immunoglobulin e increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
cardiac murmur alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
double stranded dna antibody positive alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
eosinophil count increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)
occurrences (all)	0	6
gamma-glutamyltransferase increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	2 / 141 (1.42%)	7 / 1012 (0.69%)
occurrences (all)	2	7
glucose urine present		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
haematocrit decreased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
haemoglobin urine present		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)
occurrences (all)	1	5
hepatic enzyme increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	3
helicobacter test positive		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
heart rate increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

intraocular pressure increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
mean cell volume increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
liver function test abnormal alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
liver function test increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	2 / 1012 (0.20%) 2
lymphocyte count decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
lymphocyte morphology abnormal alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
mean cell haemoglobin concentration decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	2 / 1012 (0.20%) 2
mean cell haemoglobin decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1
mean cell volume decreased alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
platelet count decreased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	4
protein urine present		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	2
platelet count increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
red blood cell morphology abnormal		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
sars-cov-2 test positive		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
treponema test positive		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
tri-iodothyronine free increased		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
urine ketone body present		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2

white blood cells urine positive alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	2 / 1012 (0.20%) 2	
weight decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2	2 / 1012 (0.20%) 2	
weight increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2	5 / 1012 (0.49%) 5	
white blood cell count decreased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
white blood cell count increased alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
Injury, poisoning and procedural complications abdominal wall wound alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
alcohol poisoning alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
ankle fracture alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
arthropod bite alternative dictionary used:			

MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	4
animal bite		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)
occurrences (all)	1	4
chemical burn of skin		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
clavicle fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
concussion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
contusion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
corneal abrasion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
epicondylitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
fall		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	6
eyelid abrasion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
fibula fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
foot fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
foreign body in ear		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
foreign body in eye		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hip fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
head injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hand fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3

limb injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
joint dislocation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4
joint injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
ligament rupture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
ligament sprain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)
occurrences (all)	1	7
lip injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
meniscus injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)
occurrences (all)	1	6
muscle strain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)
occurrences (all)	1	5
nail injury		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
overdose		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
post procedural haemorrhage		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
procedural dizziness		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	2
procedural pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4
post-traumatic neck syndrome		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
rib fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
road traffic accident		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
scar		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

radius fracture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
skin laceration		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	6
skin abrasion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
superficial injury of eye		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
suture rupture		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
soft tissue injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
sports injury		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
sunburn		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
thermal burn		
alternative dictionary used: MedDRA 27.1		

<p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>2 / 1012 (0.20%)</p> <p>occurrences (all)</p> <p>0</p> <p>3</p>			
<p>tendon injury</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>traumatic pain</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>tooth fracture</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>1 / 141 (0.71%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>1</p> <p>1</p>			
<p>vaccination complication</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>5 / 1012 (0.49%)</p> <p>occurrences (all)</p> <p>0</p> <p>10</p>			
<p>wrist fracture</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>Congenital, familial and genetic disorders</p> <p>dermoid cyst</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>Cardiac disorders</p> <p>arrhythmia</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>0 / 141 (0.00%)</p> <p>1 / 1012 (0.10%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 27.1</p>			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
coronary artery disease			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
mitral valve incompetence			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
palpitations			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
sinus bradycardia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
tachycardia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
ventricular extrasystoles			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Nervous system disorders			
dementia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
dizziness			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
disturbance in attention		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
facial paralysis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
headache		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	4 / 141 (2.84%)	23 / 1012 (2.27%)
occurrences (all)	4	31
hypogeusia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
migraine		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)
occurrences (all)	1	5
migraine with aura		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
nerve compression		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
neuropathy peripheral		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

occipital neuralgia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
parkinson's disease		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
parosmia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
piriformis syndrome		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
paraesthesia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
post herpetic neuralgia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
presyncope		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
radiculopathy		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
seizure		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
syncope			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	
occurrences (all)	0	6	
tension headache			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	
occurrences (all)	1	2	
vith nerve paralysis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	6 / 1012 (0.59%)	
occurrences (all)	1	7	
anaemia macrocytic			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
eosinophilia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	10 / 1012 (0.99%)	
occurrences (all)	1	12	
iron deficiency anaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	9 / 1012 (0.89%)	
occurrences (all)	1	10	
leukopenia			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4
lymphadenopathy		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	2 / 141 (1.42%)	2 / 1012 (0.20%)
occurrences (all)	2	2
lymphocytosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
lymphopenia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
neutropenia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
neutrophilia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
normocytic anaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
splenomegaly		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
thrombocytopenia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2

thrombocytosis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
Ear and labyrinth disorders ear pain alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) ear pruritus alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0 0 / 141 (0.00%) 0	4 / 1012 (0.40%) 4 1 / 1012 (0.10%) 1	
Eye disorders allergic keratitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) astigmatism alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) blepharitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) blepharitis allergic alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) cataract alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all) chalazion	0 / 141 (0.00%) 0 0 / 141 (0.00%) 0 1 / 141 (0.71%) 1 0 / 141 (0.00%) 0 0 / 141 (0.00%) 0 0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1 1 / 1012 (0.10%) 1 3 / 1012 (0.30%) 5 1 / 1012 (0.10%) 1 3 / 1012 (0.30%) 3	

alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
conjunctival irritation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
conjunctivitis allergic		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	4 / 141 (2.84%)	29 / 1012 (2.87%)
occurrences (all)	4	38
corneal neovascularisation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
dry eye		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)
occurrences (all)	1	5
eczema eyelids		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
erythema of eyelid		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
eyelid oedema		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
eye swelling		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
eye pruritus		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	4
eye irritation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	3
glaucoma		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
keratitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
keratoconus		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
myopia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
ocular hyperaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
periorbital dermatitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

scleritis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
vitreous floaters alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
vitreous detachment alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
visual impairment alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
vision blurred alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	4 / 1012 (0.40%) 4	
vernal keratoconjunctivitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	3 / 1012 (0.30%) 4	
xerophthalmia alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	7 / 1012 (0.69%) 7	
abdominal pain lower alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
abdominal pain upper		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
ascites		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
coeliac disease		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
colitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
constipation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	4
dental caries		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
diverticulum intestinal		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
diarrhoea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	13 / 1012 (1.28%)
occurrences (all)	0	15

enteritis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
duodenal ulcer		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
dyspepsia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4
gastrointestinal disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
gastritis erosive		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
gastritis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
haematochezia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
gastrooesophageal reflux disease		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)
occurrences (all)	1	6
haemorrhoids		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	3
intestinal vascular disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
large intestine polyp		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
malpositioned teeth		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
nausea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	9 / 1012 (0.89%)
occurrences (all)	0	9
odynophagia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	2
rectal polyp		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
stress ulcer		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
toothache		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	5

tooth impacted alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	1 / 1012 (0.10%) 1	
vomiting alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	5 / 1012 (0.49%) 5	
Hepatobiliary disorders			
alcoholic liver disease alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
cholecystitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	0 / 1012 (0.00%) 0	
cholelithiasis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	2 / 1012 (0.20%) 2	
gallbladder disorder alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	0 / 1012 (0.00%) 0	
gallbladder polyp alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
hyperbilirubinaemia alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
hepatomegaly alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
hepatic steatosis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)	
occurrences (all)	0	6	
hypertransaminasaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	
occurrences (all)	1	1	
jaundice			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
metabolic dysfunction-associated liver disease			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
metabolic dysfunction-associated steatohepatitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	17 / 1012 (1.68%)	
occurrences (all)	1	19	
acne varioliformis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
androgenetic alopecia			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
alopecia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)
occurrences (all)	1	7
alopecia areata		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	5
actinic keratosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	8
chronic cutaneous lupus erythematosus		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
dandruff		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
cutaneous calcification		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
dermatitis acneiform		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
dermatitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	4

dermal cyst		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
diffuse alopecia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
dermatitis psoriasiform		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	2	0
dermatitis allergic		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	3
dermatitis atopic		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	9 / 141 (6.38%)	67 / 1012 (6.62%)
occurrences (all)	11	98
dermatitis contact		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	2 / 141 (1.42%)	5 / 1012 (0.49%)
occurrences (all)	2	5
dry skin		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
eczema		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
eczema nummular		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
erythema		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
guttate psoriasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hyperkeratosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hyperhidrosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
ingrowing nail		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
intertrigo		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
keloid scar		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
keratosis pilaris		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2

lichen striatus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
lichenoid keratosis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
mechanical urticaria			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
milium			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
nail dystrophy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
nail bed inflammation			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
papule			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
parapsoriasis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
perioral dermatitis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
petechiae		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
photodermatitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
photosensitivity reaction		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
pityriasis rosea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	2
pruritus		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	8 / 1012 (0.79%)
occurrences (all)	0	8
pruritus allergic		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
psoriasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
rash		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	2

rash papular		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
rosacea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
seborrhoeic dermatitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)
occurrences (all)	0	9
skin discolouration		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
skin exfoliation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
skin fissures		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
skin irritation		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
skin lesion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	3	0
urticaria chronic		
alternative dictionary used: MedDRA 27.1		

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>urticaria</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>11 / 1012 (1.09%)</p> <p>11</p>	
<p>urticaria contact</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>2</p>	
<p>Renal and urinary disorders</p> <p>bladder obstruction</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>glycosuria</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>haematuria</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>5 / 1012 (0.49%)</p> <p>6</p>	
<p>nephrolithiasis</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>2 / 1012 (0.20%)</p> <p>2</p>	
<p>nephropathy toxic</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>proteinuria</p> <p>alternative dictionary used: MedDRA 27.1</p>			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>renal failure</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 141 (0.71%)</p> <p>1</p>	<p>0 / 1012 (0.00%)</p> <p>0</p>	
<p>renal impairment</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>urinary incontinence</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 141 (0.71%)</p> <p>1</p>	<p>0 / 1012 (0.00%)</p> <p>0</p>	
<p>Endocrine disorders</p> <p>androgen deficiency</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>glucocorticoid deficiency</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>1 / 1012 (0.10%)</p> <p>1</p>	
<p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 141 (0.00%)</p> <p>0</p>	<p>3 / 1012 (0.30%)</p> <p>3</p>	
<p>polycystic ovarian syndrome</p> <p>alternative dictionary used: MedDRA 27.1</p> <p>subjects affected / exposed^[19]</p> <p>occurrences (all)</p>	<p>0 / 82 (0.00%)</p> <p>0</p>	<p>1 / 513 (0.19%)</p> <p>1</p>	
<p>thyroid cyst</p> <p>alternative dictionary used: MedDRA 27.1</p>			

subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	15 / 1012 (1.48%)	
occurrences (all)	1	19	
arthritis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
arthropathy			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
back pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	14 / 1012 (1.38%)	
occurrences (all)	2	17	
costochondritis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
dupuytren's contracture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
flank pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
groin pain			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
hypercreatinaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
intervertebral disc disorder		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
intervertebral disc protrusion		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
joint swelling		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
muscle spasms		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
musculoskeletal chest pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
musculoskeletal pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
musculoskeletal stiffness		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1

myalgia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	5
neck pain		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
osteoarthritis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	6
osteoporosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
pain in extremity		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	5
rhabdomyolysis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
rotator cuff syndrome		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
scoliosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
spinal pain		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
spondylitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
tenosynovitis stenosans			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
tenosynovitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
tendonitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
synovial cyst			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Infections and infestations			
abscess of eyelid			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
acarodermatitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
acute sinusitis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
alveolar osteitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
appendicitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
ascariasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
bacterial vaginosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed ^[20]	2 / 82 (2.44%)	1 / 513 (0.19%)
occurrences (all)	3	4
blastocystis infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
campylobacter gastroenteritis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
body tinea		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
bronchitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	11 / 1012 (1.09%)
occurrences (all)	0	11

bronchitis bacterial alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
covid-19 alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	25 / 141 (17.73%) 28	156 / 1012 (15.42%) 168	
cellulitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	5 / 1012 (0.49%) 5	
cellulitis staphylococcal alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
chlamydial infection alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
chronic sinusitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	0 / 1012 (0.00%) 0	
conjunctivitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	3 / 141 (2.13%) 4	39 / 1012 (3.85%) 45	
coronavirus infection alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	3 / 1012 (0.30%) 4	
conjunctivitis bacterial alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	2 / 141 (1.42%)	3 / 1012 (0.30%)
occurrences (all)	2	4
cystitis bacterial		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	3
cystitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	5
conjunctivitis viral		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	2	1
diverticulitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
ear infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	2 / 141 (1.42%)	4 / 1012 (0.40%)
occurrences (all)	2	6
eczema infected		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
erythrasma		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
enterobiasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0

eye infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
gastrointestinal viral infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
folliculitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	8 / 1012 (0.79%)
occurrences (all)	3	9
furuncle		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	2
gastrointestinal infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	5
gastroenteritis viral		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	4
gastroenteritis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)
occurrences (all)	1	15
gingivitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0
genital herpes		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
genital herpes simplex		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	3
genital infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
giardiasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
hordeolum		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	7
herpes zoster		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	11 / 1012 (1.09%)
occurrences (all)	1	15
herpes virus infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
herpes simplex		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	2 / 141 (1.42%)	9 / 1012 (0.89%)
occurrences (all)	3	14
helicobacter infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)
occurrences (all)	1	0

helicobacter gastritis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
infected cyst			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
impetigo			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	8 / 1012 (0.79%)	
occurrences (all)	3	10	
infected dermal cyst			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	2	
infected bite			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
infectious mononucleosis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
influenza			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)	
occurrences (all)	1	12	
infusion site cellulitis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
labyrinthitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
laryngitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)
occurrences (all)	1	1
latent tuberculosis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
localised infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
lower respiratory tract infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
malassezia infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
molluscum contagiosum		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
nasal herpes		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	5

nasopharyngitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	13 / 141 (9.22%) 14	113 / 1012 (11.17%) 161	
norovirus infection alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	0 / 1012 (0.00%) 0	
nail infection alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
oesophageal candidiasis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	1 / 1012 (0.10%) 1	
onychomycosis alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1	1 / 1012 (0.10%) 1	
oral herpes alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 3	30 / 1012 (2.96%) 46	
orchitis alternative dictionary used: MedDRA 27.1 subjects affected / exposed ^[21] occurrences (all)	0 / 59 (0.00%) 0	1 / 499 (0.20%) 1	
otitis externa alternative dictionary used: MedDRA 27.1 subjects affected / exposed occurrences (all)	0 / 141 (0.00%) 0	3 / 1012 (0.30%) 4	
otitis media alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)
occurrences (all)	1	5
otitis media acute		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
paronychia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
periodontitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
pharyngitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	6
pharyngitis bacterial		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
pharyngitis streptococcal		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4
pulpitis dental		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
pneumonia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2

scarlet fever			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
respiratory tract infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
rhinitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	
occurrences (all)	1	1	
sinusitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	4 / 141 (2.84%)	15 / 1012 (1.48%)	
occurrences (all)	4	15	
skin bacterial infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	3	
skin candida			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
skin infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
subcutaneous abscess			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
staphylococcal skin infection			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
tonsillitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
tinea capitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
tinea cruris		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
tinea pedis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
tinea versicolour		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)
occurrences (all)	0	5
tracheitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
toxocariasis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
tooth infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)
occurrences (all)	0	4

tooth abscess		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)
occurrences (all)	1	2
urinary tract infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	3 / 141 (2.13%)	28 / 1012 (2.77%)
occurrences (all)	3	33
upper respiratory tract infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	7 / 141 (4.96%)	48 / 1012 (4.74%)
occurrences (all)	11	62
vaginal infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed ^[22]	0 / 82 (0.00%)	2 / 513 (0.39%)
occurrences (all)	0	2
viral upper respiratory tract infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
viral pharyngitis		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
viral infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
wound infection		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
vulvovaginal candidiasis		
alternative dictionary used: MedDRA 27.1		

subjects affected / exposed ^[23]	1 / 82 (1.22%)	2 / 513 (0.39%)	
occurrences (all)	1	2	
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
decreased appetite			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	
occurrences (all)	1	2	
diabetes mellitus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
dyslipidaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
food intolerance			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
glucose tolerance impaired			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
gout			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	
occurrences (all)	0	8	
haemochromatosis			
alternative dictionary used: MedDRA 27.1			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hypercholesterolaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)
occurrences (all)	1	3
hypophosphataemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hypokalaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
hypoglycaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hyperuricaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2
hypernatraemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)
occurrences (all)	0	1
hyperlipidaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)
occurrences (all)	0	3
hyperglycaemia		
alternative dictionary used: MedDRA 27.1		
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)
occurrences (all)	0	2

lactose intolerance			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
obesity			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	4	
periarthritis calcarea			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
vitamin d deficiency			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	

Notes:

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

Justification: 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.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 December 2020	Protocol Amendment (1): Added 48 weeks of treatment (for total of 100 weeks) to gain additional safety data on long-term exposures. Removed male contraception requirements as supported by toxicology data. Added hepatic safety monitoring section with detailed guidance. Added instructions for withholding study drug when warranted for participant safety.
14 December 2022	Protocol Amendment (2): Clarified when Study KGAK participants receive blinded and open-label study drug. Clarified unblinded interim analysis regarding Study KGAK. Included language that live vaccines are not permitted during the trial. Deleted timing requirement to report AESIs. Included that additional data will be collected in eCRF for AESIs. Included that "the investigator or designee" may discuss discontinuation of study drug or dose changes due to an AE. Included the Infections and Opportunistic Infections section. Included details related to mITT population. Included product complaints language.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported