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

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)	EMEA-002536-PIP01-18
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	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

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	34.9	32.5	
standard deviation	± 16.96	± 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

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

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

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.1

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.	

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	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
morning sickness			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed[6]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
uterine hypertonus			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed[7]	0 / 82 (0.00%)	1 / 513 (0.19%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
chest discomfort			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	3	
chest pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
fatigue			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	8 / 1012 (0.79%)	
occurrences (all)	0	9	
general physical health deterioration			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	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	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	3	
blood potassium increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
blood pressure diastolic increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
blood pressure increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	
occurrences (all)	1	3	
blood testosterone decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	0 / 1012 (0.00%)	
occurrences (all)	2	0	
blood uric acid increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
blood immunoglobulin e increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
cardiac murmur			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	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	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
mean cell volume increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
liver function test abnormal			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
liver function test increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
lymphocyte count decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
mean cell haemoglobin concentration decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
mean cell haemoglobin decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	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	1 / 141 (0.71%)	2 / 1012 (0.20%)	
occurrences (all)	1	2	
weight decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	2 / 1012 (0.20%)	
occurrences (all)	2	2	
weight increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	5 / 1012 (0.49%)	
occurrences (all)	2	5	
white blood cell count decreased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
white blood cell count increased			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
abdominal wall wound			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
alcohol poisoning			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
ankle fracture			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	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			

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

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

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	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
vitreous floaters			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
vitreous detachment			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
visual impairment			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
vision blurred			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	
occurrences (all)	1	4	
vernal keratoconjunctivitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	4	
xerophthalmia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	
occurrences (all)	1	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	1 / 141 (0.71%)	1 / 1012 (0.10%)	
occurrences (all)	1	1	
vomiting			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	
occurrences (all)	0	5	
Hepatobiliary disorders			
alcoholic liver disease			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
cholecystitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
cholelithiasis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	
occurrences (all)	0	2	
gallbladder disorder			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
gallbladder polyp			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
hyperbilirubinaemia			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	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	
milia			
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	
photodermatosis			
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			

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

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

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	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
covid-19			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	25 / 141 (17.73%)	156 / 1012 (15.42%)	
occurrences (all)	28	168	
cellulitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	
occurrences (all)	0	5	
cellulitis staphylococcal			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
chlamydial infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
chronic sinusitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
conjunctivitis			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	3 / 141 (2.13%)	39 / 1012 (3.85%)	
occurrences (all)	4	45	
coronavirus infection			
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	
occurrences (all)	1	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	13 / 141 (9.22%)	113 / 1012 (11.17%)	
occurrences (all)	14	161	
norovirus infection alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	
occurrences (all)	1	0	
nail infection alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
oesophageal candidiasis alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	
occurrences (all)	0	1	
onychomycosis alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	
occurrences (all)	1	1	
oral herpes alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	2 / 141 (1.42%)	30 / 1012 (2.96%)	
occurrences (all)	3	46	
orchitis alternative dictionary used: MedDRA 27.1			
subjects affected / exposed[21]	0 / 59 (0.00%)	1 / 499 (0.20%)	
occurrences (all)	0	1	
otitis externa alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	
occurrences (all)	0	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.
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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