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	v2 (current)
This version publication date	02 November 2025
First version publication date	03 August 2025
Version creation reason	• New data added to full data set LPV results

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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 April 2025
Is this the analysis of the primary completion data?	No

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: -

Pre-assignment

Screening 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 (Lebrikizumab Q4W and Lebrikizumab Q8W)

Period 1

Period 1 title	Primary Treatment Period (100 Weeks)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Primary Treatment Period: 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	Primary Treatment Period: 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	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: Lebrikizumab Q2W
Started	141	1012
Received at Least One Doe of Study Drug	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

Period 2	
Period 2 title	Open-Label Extension Addendum (32 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	Yes
Arm title	Open-Label Extension Addendum: Lebrikizumab Q4W
Arm description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 32 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 32 weeks.	
Arm title	Open-Label Extension Addendum: Lebrikizumab Q8W
Arm description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 8 weeks (Q8W) up to 32 weeks.	
Arm type	Experimental

Investigational medicinal product name	Lebrikizumab Q8W
Investigational medicinal product code	LY3650150
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Lebrikizumab, subcutaneous injection administered every 8 weeks (Q8W) up to 32 weeks.

Number of subjects in period 2[1]	Open-Label Extension Addendum: Lebrikizumab Q4W	Open-Label Extension Addendum: Lebrikizumab Q8W
Started	52	51
Received at Least 1 Dose of Study Drug	52	51
Completed	51	49
Not completed	1	2
Consent withdrawn by subject	-	1
Lost to follow-up	-	1
Protocol deviation	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who completed the 100-week primary treatment period, regardless of their previous treatment regimen (Lebrikizumab Q2W or Q4W), had the option to enter the open-label extension addendum to receive Lebrikizumab 250 mg Q4W or Q8W.

Baseline characteristics

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

Reporting group values	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: 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	Primary Treatment Period: Lebrikizumab Q4W
Reporting group description:	
250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.	
Reporting group title	Primary Treatment Period: Lebrikizumab Q2W
Reporting group description:	
250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.	
Reporting group title	Open-Label Extension Addendum: Lebrikizumab Q4W
Reporting group description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 32 weeks.	
Reporting group title	Open-Label Extension Addendum: Lebrikizumab Q8W
Reporting group description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 8 weeks (Q8W) up to 32 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	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: 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	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: 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	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: 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:	
Primary Treatment Period: up to 110 Weeks; Open-Label Extension Addendum: up to 42 weeks	
Adverse event reporting additional description:	
All participants who received at least one dose of study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	28.0

Reporting groups	
Reporting group title	Primary Treatment Period: Lebrikizumab Q4W
Reporting group description:	
250 milligrams (mg) of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 100 weeks.	
Reporting group title	Primary Treatment Period: Lebrikizumab Q2W
Reporting group description:	
250 mg Lebrikizumab, subcutaneous injection administered every 2 weeks (Q2W) up to 100 weeks.	
Reporting group title	Open-Label Extension Addendum: Lebrikizumab Q4W
Reporting group description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 4 weeks (Q4W) up to 32 weeks.	
Reporting group title	Open-Label Extension Addendum: Lebrikizumab Q8W
Reporting group description:	
250 mg of Lebrikizumab, subcutaneous injection administered every 8 weeks (Q8W) up to 32 weeks.	

Serious adverse events	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: Lebrikizumab Q2W	Open-Label Extension Addendum: Lebrikizumab Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 141 (3.55%)	45 / 1012 (4.45%)	0 / 52 (0.00%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
invasive breast carcinoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neuroendocrine tumour			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
influenza like illness			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
anaphylactic shock			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
food allergy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary mass			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression suicidal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
blood potassium decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
accident			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subdural haematoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
splenic rupture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cervical cord compression			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sudden visual loss			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
large intestine polyp			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
rotator cuff syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval abscess			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
ketoacidosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Open-Label Extension Addendum: Lebrikizumab Q8W		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
invasive breast carcinoma			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrointestinal stromal tumour				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
endometrial adenocarcinoma				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neuroendocrine tumour				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ovarian germ cell teratoma benign				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatic carcinoma metastatic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostate cancer				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

General disorders and administration site conditions			
influenza like illness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
death			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
anaphylactic shock			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
food allergy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pleural effusion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

pulmonary mass				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
attention deficit hyperactivity disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
major depression				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
depression suicidal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
depression				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
mixed anxiety and depressive disorder				
alternative dictionary used:				

MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
blood potassium decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
ankle fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
accident				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hip fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
multiple injuries				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
radius fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
subdural haematoma				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
splenic rupture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
atrial fibrillation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
cervical cord compression				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
seizure				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
cataract				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sudden visual loss				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
large intestine polyp				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hiatus hernia				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
small intestinal obstruction				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
cholelithiasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
dermatitis atopic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
stevens-johnson syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
rotator cuff syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
bacteraemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
appendicitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
covid-19				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vulval abscess				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
subcutaneous abscess			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
ketoacidosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypokalaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Primary Treatment Period: Lebrikizumab Q4W	Primary Treatment Period: Lebrikizumab Q2W	Open-Label Extension Addendum: Lebrikizumab Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 141 (63.12%)	638 / 1012 (63.04%)	17 / 52 (32.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
fibroadenoma of breast			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
melanocytic naevus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
lipoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pyogenic granuloma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
skin papilloma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
deep vein thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
essential hypertension			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
haematoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypertension			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	15 / 1012 (1.48%)	0 / 52 (0.00%)
occurrences (all)	0	15	0
orthostatic hypotension			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
venous thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
anembryonic gestation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
morning sickness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
uterine hypertonus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
chest discomfort			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
chest pain			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	1 / 52 (1.92%)
occurrences (all)	0	3	1
fatigue			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	9 / 1012 (0.89%)	0 / 52 (0.00%)
occurrences (all)	0	10	0
general physical health deterioration			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
injection site pruritus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
influenza like illness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
injection site bruising			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
injection site haematoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
injection site pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
injection site rash			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0

injection site reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)	0 / 52 (0.00%)
occurrences (all)	2	32	0
injection site swelling			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
malaise			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
peripheral swelling			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pyrexia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
swelling face			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vaccination site pain			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	8 / 1012 (0.79%)	0 / 52 (0.00%)
occurrences (all)	0	16	0
vaccination site reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vascular stent stenosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
allergy to arthropod bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
allergy to venom			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
anaphylactic reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
dust allergy			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
food allergy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
hypersensitivity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
multiple allergies			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
seasonal allergy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	9 / 1012 (0.89%)	0 / 52 (0.00%)
occurrences (all)	0	10	0
Reproductive system and breast disorders			
abnormal uterine bleeding			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
breast mass			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
dysmenorrhoea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	26	0
erectile dysfunction			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
fibrocystic breast disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
heavy menstrual bleeding			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
menstruation irregular			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
menopausal symptoms			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ovarian cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
prostatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
testicular cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vaginal discharge			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
asthma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	1	6	0
bronchial hyperreactivity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
bronchospasm			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
cough			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)	0 / 52 (0.00%)
occurrences (all)	1	13	0
epistaxis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
dyspnoea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypoxia			
alternative dictionary used:			

MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nasal septum deviation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nasal polyps			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
oropharyngeal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	1	6	0
rhinitis allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	1 / 52 (1.92%)
occurrences (all)	0	5	1
rhinorrhoea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
sinus congestion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
respiratory tract congestion			
subjects affected / exposed	0 / 141 (0.00%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
alcohol abuse			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
bipolar i disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
anxiety			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	11 / 1012 (1.09%)	0 / 52 (0.00%)
occurrences (all)	1	11	0
apathy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
attention deficit hyperactivity			

disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	1 / 52 (1.92%)
occurrences (all)	0	2	1
autism spectrum disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	10 / 1012 (0.99%)	0 / 52 (0.00%)
occurrences (all)	0	10	0
insomnia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	1	7	0
libido decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mania			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
major depression			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mixed anxiety and depressive disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
sleep disorder due to general medical condition, insomnia type			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	17 / 1012 (1.68%)	0 / 52 (0.00%)
occurrences (all)	0	18	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	0	8	0
bilirubin urine			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
bilirubin urine present			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
blood bicarbonate decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood creatinine increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
blood glucose decreased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
blood immunoglobulin e increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood iron decreased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood lactate dehydrogenase increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
blood potassium increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
blood pressure diastolic increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood pressure increased alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0

blood testosterone decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood uric acid increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
cardiac murmur			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
double stranded dna antibody positive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
eosinophil count increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	2	7	0
haematocrit decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
glucose urine present			

alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
haemoglobin urine present			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	1	5	0
heart rate increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
helicobacter test positive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
intraocular pressure increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mean cell volume increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mean cell volume decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mean cell haemoglobin decreased			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mean cell haemoglobin concentration decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
liver function test increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
liver function test abnormal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
platelet count decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
platelet count increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
protein urine present			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0

red blood cell morphology abnormal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
syphilis test positive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tri-iodothyronine free increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
urine ketone body present			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
weight decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	2	2	0
white blood cell count decreased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
white blood cell count increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
white blood cells urine positive			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
weight increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	2	5	0
Injury, poisoning and procedural complications			
abdominal wall wound			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ankle fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
alcohol poisoning			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
animal bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
arthropod bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
chemical burn of skin			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
clavicle fracture			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
concussion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	1 / 52 (1.92%)
occurrences (all)	1	3	1
contusion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
corneal abrasion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
epicondylitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
eyelid abrasion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
fall			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
fibula fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
foot fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0

foreign body in ear			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
foreign body in eye			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hand fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
head injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hip fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
joint dislocation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
joint injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ligament rupture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lip injury			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
limb injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
ligament sprain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	1	7	0
meniscus injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	1	6	0
nail injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
muscle strain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	1	5	0
overdose			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
procedural pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
radius fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	1 / 52 (1.92%)
occurrences (all)	0	2	1

post procedural haemorrhage			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
procedural dizziness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
rib fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
road traffic accident			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
scar			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
skin abrasion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
tendon injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
skin laceration			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
soft tissue injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
sports injury			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
sunburn			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
superficial injury of eye			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
suture rupture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
thermal burn			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
tooth fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
traumatic pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

vaccination complication			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	10	0
wrist fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
Congenital, familial and genetic disorders			
dermoid cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
accessory navicular syndrome			
subjects affected / exposed	0 / 141 (0.00%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
arrhythmia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
atrial fibrillation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
coronary artery disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
mitral valve incompetence			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
palpitations			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
sinus bradycardia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tachycardia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
disturbance in attention			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
dementia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
dizziness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
facial paralysis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
headache			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	4 / 141 (2.84%)	25 / 1012 (2.47%)	1 / 52 (1.92%)
occurrences (all)	4	33	1
hypogeusia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
migraine with aura			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	1 / 52 (1.92%)
occurrences (all)	1	5	1
occipital neuralgia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
nerve compression			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
neuropathy peripheral			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
paraesthesia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
parkinson's disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

parosmia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
piriformis syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
radiculopathy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
presyncope			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
seizure			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
syncope			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
tension headache			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
vith nerve paralysis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	1	7	0
anaemia macrocytic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
eosinophilia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	10 / 1012 (0.99%)	0 / 52 (0.00%)
occurrences (all)	1	12	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	9 / 1012 (0.89%)	0 / 52 (0.00%)
occurrences (all)	1	10	0
leukopenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
lymphopenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
lymphocytosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	2 / 141 (1.42%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	2	2	0
normocytic anaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
neutropenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
neutrophilia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
splenomegaly			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
thrombocytopenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
thrombocytosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
ear pruritus			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
allergic keratitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
astigmatism			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blepharitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	5	0
blepharitis allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
corneal neovascularisation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
cataract			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	1 / 52 (1.92%)
occurrences (all)	0	3	1
chalazion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
conjunctival irritation			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	4 / 141 (2.84%)	29 / 1012 (2.87%)	0 / 52 (0.00%)
occurrences (all)	4	39	0
dry eye			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	1	5	0
eczema eyelids			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
eye irritation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
eye pruritus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
eye swelling			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
eyelid oedema			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0

glaucoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
keratitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
keratoconus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
myopia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
periorbital dermatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
scleritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vernal keratoconjunctivitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
vision blurred			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
visual impairment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vitreous detachment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
vitreous floaters			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
xerophthalmia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
abdominal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	1	7	0
abdominal pain lower			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
abdominal pain upper			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
ascites			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
anorectal polyp			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
coeliac disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
colitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
constipation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
dental caries			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
diarrhoea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	13 / 1012 (1.28%)	0 / 52 (0.00%)
occurrences (all)	0	15	0
duodenal ulcer			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0

dyspepsia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
enteritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
diverticulum intestinal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
gastritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	1 / 52 (1.92%)
occurrences (all)	0	2	1
gastritis erosive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	1	6	0
haematochezia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
gastric mucosa erythema			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
hiatus hernia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
intestinal vascular disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
large intestine polyp			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
malpositioned teeth			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	9 / 1012 (0.89%)	0 / 52 (0.00%)
occurrences (all)	0	9	0
odynophagia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
stress ulcer			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tooth impacted			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0

toothache			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
vomiting			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
Hepatobiliary disorders			
alcoholic liver disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
cholecystitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
cholelithiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
gallbladder polyp			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
gallbladder disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
hepatomegaly			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hyperbilirubinaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypertransaminasaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
jaundice			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
metabolic dysfunction-associated steatohepatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
metabolic dysfunction-associated liver disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	17 / 1012 (1.68%)	1 / 52 (1.92%)
occurrences (all)	1	19	1
acne varioliformis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
alopecia			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	1	7	0
alopecia areata			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
androgenetic alopecia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
actinic keratosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	8	0
chronic cutaneous lupus erythematosus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
cutaneous calcification			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
dandruff			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
dermal cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
dermatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0

dermatitis acneiform			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
dermatitis allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
dermatitis atopic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	9 / 141 (6.38%)	70 / 1012 (6.92%)	0 / 52 (0.00%)
occurrences (all)	12	102	0
dermatitis contact			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	2	5	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
dry skin			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
eczema			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
eczema nummular			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
erythema			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
guttate psoriasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hyperkeratosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ingrowing nail			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
hyperhidrosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
intertrigo			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
keloid scar			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
keratosis pilaris			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0

lichen striatus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lichenoid keratosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
mechanical urticaria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nail dystrophy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nail bed inflammation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
milia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
papule			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
parapsoriasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
perioral dermatitis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
petechiae			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
photodermatosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
photosensitivity reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
pityriasis rosea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
pruritus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	8 / 1012 (0.79%)	0 / 52 (0.00%)
occurrences (all)	0	8	0
pruritus allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
psoriasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
rash			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0

rash papular			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
rosacea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	0	9	0
skin discolouration			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
skin exfoliation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
skin fissures			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
skin irritation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
skin lesion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	3	0	0
urticaria			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	11 / 1012 (1.09%)	0 / 52 (0.00%)
occurrences (all)	0	11	0
urticaria chronic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
urticaria contact			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
rash vesicular			
subjects affected / exposed	0 / 141 (0.00%)	0 / 1012 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
ingrown hair			
subjects affected / exposed	0 / 141 (0.00%)	0 / 1012 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Renal and urinary disorders			
bladder obstruction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
glycosuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
haematuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
nephrolithiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
nephropathy toxic			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
proteinuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
renal failure			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
renal impairment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
urinary incontinence			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
androgen deficiency			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
glucocorticoid deficiency			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypothyroidism			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
polycystic ovarian syndrome			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
thyroid cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	15 / 1012 (1.48%)	0 / 52 (0.00%)
occurrences (all)	1	19	0
arthritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
arthropathy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
back pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	14 / 1012 (1.38%)	0 / 52 (0.00%)
occurrences (all)	2	17	0
costochondritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
dupuytren's contracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
flank pain			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
groin pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
hypercreatinaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
intervertebral disc disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
joint swelling			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
myalgia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

musculoskeletal chest pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
muscle spasms			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
osteoarthritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	6	0
osteoporosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
neck pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
pain in extremity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
rhabdomyolysis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
scoliosis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
spinal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
spondylitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
synovial cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tendonitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tenosynovitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
abscess of eyelid			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
acute sinusitis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
alveolar osteitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
appendicitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
ascariasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	3	4	0
covid-19			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	26 / 141 (18.44%)	159 / 1012 (15.71%)	1 / 52 (1.92%)
occurrences (all)	29	172	1
body tinea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
bronchitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	11 / 1012 (1.09%)	0 / 52 (0.00%)
occurrences (all)	0	11	0
bronchitis bacterial			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

blastocystis infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
cellulitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
chlamydial infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
chronic sinusitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
conjunctivitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	3 / 141 (2.13%)	39 / 1012 (3.85%)	1 / 52 (1.92%)
occurrences (all)	4	45	2
conjunctivitis bacterial			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	2	4	0
conjunctivitis viral			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	2	1	0
cystitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
cystitis bacterial			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
coronavirus infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
diverticulitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	2	6	0
eczema infected			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
enterobiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
erythrasma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

eye infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
folliculitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	11 / 1012 (1.09%)	1 / 52 (1.92%)
occurrences (all)	3	12	1
furuncle			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
gastroenteritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	13 / 1012 (1.28%)	0 / 52 (0.00%)
occurrences (all)	1	16	0
gastroenteritis viral			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	4	0
gastrointestinal infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
gastrointestinal viral infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
genital herpes			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
genital herpes simplex			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
genital infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
giardiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
gingivitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
helicobacter infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
herpes simplex			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	10 / 1012 (0.99%)	0 / 52 (0.00%)
occurrences (all)	3	15	0
herpes virus infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
herpes zoster			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	11 / 1012 (1.09%)	0 / 52 (0.00%)
occurrences (all)	1	15	0

hordeolum			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
impetigo			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	8 / 1012 (0.79%)	0 / 52 (0.00%)
occurrences (all)	3	10	0
infected bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
infected cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
infected dermal cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
infectious mononucleosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	12 / 1012 (1.19%)	0 / 52 (0.00%)
occurrences (all)	1	12	0
infusion site cellulitis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
labyrinthitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
laryngitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
latent tuberculosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
malassezia infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	1 / 52 (1.92%)
occurrences (all)	0	2	1
localised infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	13 / 141 (9.22%)	115 / 1012 (11.36%)	2 / 52 (3.85%)
occurrences (all)	14	165	2
nasal herpes			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	5	0

nail infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
molluscum contagiosum			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
norovirus infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
oesophageal candidiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
onychomycosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
oral herpes			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	2 / 141 (1.42%)	30 / 1012 (2.96%)	0 / 52 (0.00%)
occurrences (all)	3	46	0
orchitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
otitis externa			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
otitis media			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	1 / 141 (0.71%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	1	5	0
otitis media acute			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pneumonia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
paronychia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
periodontitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	6 / 1012 (0.59%)	0 / 52 (0.00%)
occurrences (all)	0	7	0
pharyngitis bacterial			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
respiratory tract infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0

pulpitis dental			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
rhinitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
rhinovirus infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
scabies			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
scarlet fever			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	4 / 141 (2.84%)	15 / 1012 (1.48%)	0 / 52 (0.00%)
occurrences (all)	4	15	0
skin bacterial infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
skin candida			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
subcutaneous abscess			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
skin infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
tinea capitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
tinea cruris			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tinea pedis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
tinea versicolour			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	5 / 1012 (0.49%)	0 / 52 (0.00%)
occurrences (all)	0	5	0
tonsillitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
tooth abscess			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	1 / 52 (1.92%)
occurrences (all)	1	2	1

tooth infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	4 / 1012 (0.40%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
toxocariasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
tracheitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	3 / 141 (2.13%)	30 / 1012 (2.96%)	0 / 52 (0.00%)
occurrences (all)	3	35	0
vaginal infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
viral infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
viral pharyngitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	7 / 141 (4.96%)	49 / 1012 (4.84%)	1 / 52 (1.92%)
occurrences (all)	11	63	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
wound infection			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
staphylococcal infection			
subjects affected / exposed	0 / 141 (0.00%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
dehydration			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
diabetes mellitus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	1 / 52 (1.92%)
occurrences (all)	0	3	1
dyslipidaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
food intolerance			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
glucose tolerance impaired			

alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
gout			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	7 / 1012 (0.69%)	0 / 52 (0.00%)
occurrences (all)	0	8	0
haemochromatosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
histamine intolerance			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	0 / 1012 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 141 (0.71%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
hyperglycaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
hyperlipidaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	3 / 1012 (0.30%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
hypernatraemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hyperuricaemia			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
hypoglycaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypokalaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
hypophosphataemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
lactose intolerance			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
obesity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	4	0
periarthritis calcarea			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	1 / 1012 (0.10%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
vitamin d deficiency			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 141 (0.00%)	2 / 1012 (0.20%)	0 / 52 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Open-Label Extension Addendum: Lebrikizumab Q8W		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 51 (25.49%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
basal cell carcinoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
fibroadenoma of breast			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
melanocytic naevus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
lipoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
pyogenic granuloma			

alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
seborrhoeic keratosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
skin papilloma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
deep vein thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
essential hypertension			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
haematoma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hypertension			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
orthostatic hypotension			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
raynaud's phenomenon			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
venous thrombosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
anembryonic gestation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
morning sickness			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
uterine hypertonus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
chest discomfort			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
chest pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
fatigue				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
general physical health deterioration				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site pruritus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
influenza like illness				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site bruising				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site haematoma				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

injection site rash				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site reaction				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
injection site swelling				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
malaise				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
peripheral swelling				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pyrexia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
swelling face				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vaccination site pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vaccination site reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vascular stent stenosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
allergy to arthropod bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
allergy to venom			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
anaphylactic reaction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
drug hypersensitivity			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dust allergy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
food allergy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypersensitivity				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
multiple allergies				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
seasonal allergy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Reproductive system and breast disorders				
abnormal uterine bleeding				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
breast mass				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dysmenorrhoea				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
erectile dysfunction				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
fibrocystic breast disease				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
heavy menstrual bleeding				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
menstruation irregular				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
menopausal symptoms				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ovarian cyst				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
prostatitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
testicular cyst				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

vaginal discharge			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vaginal haemorrhage			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
asthma			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
bronchial hyperreactivity			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
bronchospasm			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
epistaxis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
dyspnoea			
alternative dictionary used:			

MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypoxia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nasal septum deviation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nasal polyps				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nasal congestion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
oropharyngeal pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rhinitis allergic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rhinorrhoea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sinus congestion				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sleep apnoea syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tonsillar hypertrophy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
upper respiratory tract inflammation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
respiratory tract congestion				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Psychiatric disorders				
alcohol abuse				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
alcohol withdrawal syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
bipolar i disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
anxiety				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
apathy				

alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
attention deficit hyperactivity disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
autism spectrum disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
depression				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
insomnia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
libido decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mania				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
major depression				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mixed anxiety and depressive disorder				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sleep disorder due to general medical condition, insomnia type				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Investigations				
alanine aminotransferase increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
bilirubin urine				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
bilirubin urine present				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood alkaline phosphatase increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood bicarbonate decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood cholesterol increased				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood creatine phosphokinase increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood creatinine increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood glucose decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood immunoglobulin e increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood iron decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood lactate dehydrogenase increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood potassium increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood pressure diastolic increased				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood pressure increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood testosterone decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood thyroid stimulating hormone increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blood uric acid increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
cardiac murmur				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
double stranded dna antibody positive				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eosinophil count increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
haematocrit decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
glucose urine present				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
haemoglobin urine present				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
heart rate increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
helicobacter test positive				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hepatic enzyme increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
intraocular pressure increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mean cell volume increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

mean cell volume decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mean cell haemoglobin decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mean cell haemoglobin concentration decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lymphocyte morphology abnormal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lymphocyte count decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
liver function test increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
liver function test abnormal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
platelet count decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
platelet count increased				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
protein urine present				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
red blood cell morphology abnormal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sars-cov-2 test positive				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
syphilis test positive				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tri-iodothyronine free increased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
urine ketone body present				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
weight decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
white blood cell count decreased				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

white blood cell count increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
white blood cells urine positive			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
weight increased			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
abdominal wall wound			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
ankle fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
alcohol poisoning			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
animal bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
arthropod bite			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
chemical burn of skin			
alternative dictionary used:			

MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
clavicle fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
concussion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
contusion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
corneal abrasion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
epicondylitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eyelid abrasion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
fall				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
fibula fracture				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
foot fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
foreign body in ear				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
foreign body in eye				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hand fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
head injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hip fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
joint dislocation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
joint injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

ligament rupture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lip injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
limb injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ligament sprain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
meniscus injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nail injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
muscle strain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
overdose				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
procedural pain				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
radius fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
post procedural haemorrhage				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
post-traumatic neck syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
procedural dizziness				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rib fracture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
road traffic accident				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
scar				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin abrasion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

tendon injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin laceration				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
soft tissue injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sports injury				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sunburn				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
superficial injury of eye				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
suture rupture				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
thermal burn				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tooth fracture				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
traumatic pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vaccination complication			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
wrist fracture			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
dermoid cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
accessory navicular syndrome			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Cardiac disorders			
arrhythmia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
atrial fibrillation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
coronary artery disease			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
mitral valve incompetence			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
palpitations			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
sinus bradycardia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
tachycardia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
ventricular extrasystoles			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
disturbance in attention			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
dementia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
dizziness			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
facial paralysis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
headache				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
hypogeusia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
migraine with aura				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
migraine				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
occipital neuralgia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nerve compression				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
neuropathy peripheral				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

paraesthesia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
parkinson's disease				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
parosmia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
piriformis syndrome				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
radiculopathy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
post herpetic neuralgia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
presyncope				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
seizure				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
syncope				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
tension headache			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vith nerve paralysis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
anaemia macrocytic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
eosinophilia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
iron deficiency anaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
leukopenia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
lymphopenia			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lymphocytosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lymphadenopathy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
normocytic anaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
neutropenia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
neutrophilia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
splenomegaly				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
thrombocytopenia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
thrombocytosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
ear pruritus			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Eye disorders			
allergic keratitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
astigmatism			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
blepharitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
blepharitis allergic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
corneal neovascularisation			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
cataract			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
chalazion			

alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
conjunctival irritation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
conjunctivitis allergic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dry eye				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eczema eyelids				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
erythema of eyelid				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eye irritation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eye pruritus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eye swelling				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eyelid oedema				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
glaucoma				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
keratitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
keratoconus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
myopia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ocular hyperaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
periorbital dermatitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
scleritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

vernal keratoconjunctivitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vision blurred			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
visual impairment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vitreous detachment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vitreous floaters			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
xerophthalmia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
abdominal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
abdominal pain lower			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
abdominal pain upper				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ascites				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
anorectal polyp				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
coeliac disease				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
colitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
constipation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dental caries				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
diarrhoea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

duodenal ulcer				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dyspepsia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
enteritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
diverticulum intestinal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastritis erosive				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
haematochezia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastric mucosa erythema				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
haemorrhoids				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hiatus hernia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
intestinal vascular disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
large intestine polyp				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
malpositioned teeth				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nausea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
odynophagia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
stress ulcer				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

tooth impacted			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
toothache			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
vomiting			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
alcoholic liver disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
cholecystitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
cholelithiasis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
gallbladder polyp			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
gallbladder disorder			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hepatic steatosis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hepatomegaly			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hyperbilirubinaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hypertransaminasaemia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
jaundice			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
metabolic dysfunction-associated steatohepatitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
metabolic dysfunction-associated liver disease			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
acne varioliformis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
alopecia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
alopecia areata				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
androgenetic alopecia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
actinic keratosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
chronic cutaneous lupus erythematosus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
cutaneous calcification				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dandruff				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dermal cyst				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

dermatitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dermatitis acneiform				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dermatitis allergic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dermatitis atopic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
dermatitis contact				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
dermatitis psoriasiform				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
diffuse alopecia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dry skin				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eczema				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eczema nummular				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
erythema				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
guttate psoriasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hyperkeratosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ingrowing nail				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hyperhidrosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
intertrigo				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
keloid scar				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

keratosis pilaris				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lichen striatus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lichenoid keratosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
mechanical urticaria				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nail dystrophy				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nail bed inflammation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
milia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
papule				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
parapsoriasis				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
perioral dermatitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
petechiae				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
photodermatosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
photosensitivity reaction				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pityriasis rosea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pruritus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pruritus allergic				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
psoriasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

rash				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rash papular				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rosacea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
seborrhoeic dermatitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin discolouration				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin exfoliation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin fissures				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin irritation				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin lesion				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
urticaria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
urticaria chronic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
urticaria contact			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
rash vesicular			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
ingrown hair			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
bladder obstruction			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
glycosuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
haematuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
nephrolithiasis			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
nephropathy toxic			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
proteinuria			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
renal failure			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
renal impairment			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
urinary incontinence			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
androgen deficiency			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
glucocorticoid deficiency			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
hypothyroidism			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
polycystic ovarian syndrome			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	0		
thyroid cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
arthritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
arthropathy			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
costochondritis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
dupuytren's contracture			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
flank pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
groin pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypercreatinaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
intervertebral disc disorder				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
intervertebral disc protrusion				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
joint swelling				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
myalgia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
musculoskeletal stiffness				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

musculoskeletal pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
musculoskeletal chest pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
muscle spasms				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
osteoarthritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
osteoporosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
neck pain				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pain in extremity				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rhabdomyolysis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rotator cuff syndrome				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
scoliosis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
spinal pain			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
spondylitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
synovial cyst			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
tendonitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
tenosynovitis stenosans			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
tenosynovitis			
alternative dictionary used: MedDRA 28.0			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Infections and infestations			
abscess of eyelid			
alternative dictionary used: MedDRA 28.0			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
acute sinusitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
alveolar osteitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
appendicitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ascariasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
bacterial vaginosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
covid-19				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
body tinea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
bronchitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

bronchitis bacterial				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
blastocystis infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
campylobacter gastroenteritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
cellulitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
cellulitis staphylococcal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
chlamydial infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
chronic sinusitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
conjunctivitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
conjunctivitis bacterial				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
conjunctivitis viral				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
cystitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
cystitis bacterial				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
coronavirus infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
diverticulitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
ear infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eczema infected				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
enterobiasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

erythrasma				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
eye infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
folliculitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
furuncle				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastroenteritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastroenteritis viral				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastrointestinal infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gastrointestinal viral infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
genital herpes				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
genital herpes simplex				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
genital infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
giardiasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gingivitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
helicobacter gastritis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
helicobacter infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
herpes simplex				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
herpes virus infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

herpes zoster				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hordeolum				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
impetigo				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infected bite				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infected cyst				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infected dermal cyst				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infectious mononucleosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
influenza				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
infusion site cellulitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
labyrinthitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
laryngitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
latent tuberculosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
malassezia infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lower respiratory tract infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
localised infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nasopharyngitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

nasal herpes				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
nail infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
molluscum contagiosum				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
norovirus infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
oesophageal candidiasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
onychomycosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
oral herpes				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
orchitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
otitis externa				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
otitis media				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
otitis media acute				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pneumonia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
paronychia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
periodontitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pharyngitis bacterial				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pharyngitis streptococcal				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

respiratory tract infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
pulpitis dental				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rhinitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
rhinovirus infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
scabies				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
scarlet fever				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
sinusitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin bacterial infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin candida				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
staphylococcal skin infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
subcutaneous abscess				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
skin infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tinea capitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tinea cruris				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tinea pedis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tinea versicolour				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
tonsillitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

tooth abscess				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tooth infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
toxocariasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
tracheitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
urinary tract infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
vaginal infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
viral infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
viral pharyngitis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
viral upper respiratory tract infection				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
upper respiratory tract infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
vulvovaginal candidiasis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
wound infection				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
staphylococcal infection				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Metabolism and nutrition disorders				
decreased appetite				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dehydration				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
diabetes mellitus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
dyslipidaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
food intolerance				

alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
glucose tolerance impaired				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
gout				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
haemochromatosis				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
histamine intolerance				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypercholesterolaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hyperglycaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hyperlipidaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypernatraemia				
alternative dictionary used: MedDRA 28.0				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hyperuricaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypoglycaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypokalaemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
hypophosphataemia				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
lactose intolerance				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
obesity				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
periarthritis calcarea				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
type 2 diabetes mellitus				
alternative dictionary used: MedDRA 28.0				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

vitamin d deficiency alternative dictionary used: MedDRA 28.0 subjects affected / exposed occurrences (all)	 0 / 51 (0.00%) 0		

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.
17 November 2023	Protocol Addendum 11: This addendum added a Q8W dosing regimen for lebrikizumab to Study KGAA via extending the study treatment period by an additional 32 weeks beyond the main protocol. This addendum applies only to Study KGAA participants who meet the addendum entry criteria and are included in the study sites in the following countries: Australia, Canada, Korea, Mexico, Singapore, Taiwan, and the United States.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported