Clinical trial results:
A Multicenter, Long-Term Extension to Evaluate the Long Term Safety and Maintenance of Treatment Effect of Mirikizumab in Patients with Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2017-003299-30
Trial protocol	DE CZ HU PL FR GB ES IT
Global end of trial date	07 February 2022

Results information

Result version number	v1 (current)
This version publication date	22 February 2023
First version publication date	22 February 2023

Trial information

Trial identification

Sponsor protocol code	I6T-MC-AMAH

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03556202
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16491

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 February 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the long-term safety and maintenance of efficacy of mirikizumab in participants with moderate-to-severe plaque psoriasis.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2018
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	Argentina: 85
Country: Number of subjects enrolled	Australia: 56
Country: Number of subjects enrolled	Canada: 94
Country: Number of subjects enrolled	Czechia: 88
Country: Number of subjects enrolled	France: 53
Country: Number of subjects enrolled	Germany: 243
Country: Number of subjects enrolled	Hungary: 70
Country: Number of subjects enrolled	Israel: 42
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Japan: 162
Country: Number of subjects enrolled	Mexico: 71
Country: Number of subjects enrolled	Poland: 279
Country: Number of subjects enrolled	Russian Federation: 46
Country: Number of subjects enrolled	Korea, Republic of: 105
Country: Number of subjects enrolled	Spain: 70
Country: Number of subjects enrolled	Taiwan: 53
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	United States: 397
Worldwide total number of subjects	1936
EEA total number of subjects	820

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1730
From 65 to 84 years	205
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants who completed an originating study: I6T-MC-AMAF (NCT02899988), I6T-MC-AMAK (NCT03482011) and I6T-MC-AMAJ (NCT03535194) were eligible for enrollment into study AMAH.

Period 1

Period 1 title	Extension Treatment Period
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Initially double-blind (until original, pivotal studies AMAK [NCT03482011] and AMAJ [NCT03535194] are locked and unblinded), then open-label.

Arms

Are arms mutually exclusive?	Yes
Arm title	125 milligram (mg) Mirikizumab Q8W

Arm description:

Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 125 mg mirikizumab administered SC Q8W.

Arm title	250 mg Mirikizumab Q8W Excluding Secukinumab

Arm description:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

Arm title	Secukinumab/250 mg Mirikizumab Q8W

Arm description:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

Arm type	Experimental

Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

Number of subjects in period 1	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W
Started	527	1020	389
Received at Least One Dose of Study Drug	527	1020	389
From AMAF	35	132	0
From AMAK	83	390	0
From AMAJ	409	498	389
Completed	0	0	0
Not completed	527	1020	389
Adverse event, serious fatal	2	6	-
Consent withdrawn by subject	22	47	22
Physician decision	-	8	2
Adverse event, non-fatal	18	14	9
Due to Exclusion Criteria of AMAJ study	-	-	1
Pregnancy	2	4	3
Sponsor Decision	-	1	-
Study Terminated by Sponsor	469	907	331
Lost to follow-up	9	20	2
Lack of efficacy	5	12	18
Protocol deviation	-	1	1

Period 2

Period 2 title	Follow-Up Period (12 weeks)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No

Arm title	125 milligram (mg) Mirikizumab Q8W Follow-up Period

Arm description:

Participants did not receive any intervention in post- treatment follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period

Arm description:

Participants did not receive any intervention in post- treatment follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Secukinumab/250 mg Mirikizumab Q8W Follow-up Period

Arm description:

Participants did not receive any intervention in post- treatment follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	125 milligram (mg) Mirikizumab Q8W Follow-up Period	250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period	Secukinumab/250 mg Mirikizumab Q8W Follow-up Period
Started	453	861	333
Completed	0	0	0
Not completed	453	861	333
Adverse event, serious fatal	1	-	-
Physician decision	-	3	1
To meet exclusion criteria of the AMAJ study	-	-	1
Site Terminated by Sponsor	-	1	-
Study Terminated by Sponsor	396	750	273
Second follow-up not done, unable to reach patient	-	-	1
Study discontinued by sponsor	-	2	1
Study terminated & subject missed follow-up visit	-	1	-
Second follow-up visit: Patient refused	-	1	-
Consent withdrawn by subject	36	65	31
Adverse event, non-fatal	11	11	8
Pregnancy	1	4	1
Lost to follow-up	4	14	3
Lack of efficacy	4	9	13

Baseline characteristics

Reporting groups	
Reporting group title	125 milligram (mg) Mirikizumab Q8W
Reporting group description:	
Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).	
Reporting group title	250 mg Mirikizumab Q8W Excluding Secukinumab
Reporting group description:	
Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).	
Reporting group title	Secukinumab/250 mg Mirikizumab Q8W
Reporting group description:	
Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.	

Reporting group values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W
Number of subjects	527	1020	389
Age categorical			
Units: Subjects			
Age continuous			
All randomized participants.			
Units: years			
arithmetic mean	47.90	47.00	46.50
standard deviation	± 13.81	± 12.87	± 14.41
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	159	309	110
Male	368	711	279
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	29	63	20
Not Hispanic or Latino	79	150	53
Unknown or Not Reported	419	807	316
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	15	48	2
Asian	89	217	63
Native Hawaiian or Other Pacific Islander	1	1	1
Black or African American	5	18	6
White	415	734	315
More than one race	2	2	2
Unknown or Not Reported	0	0	0
Region of Enrollment			

All randomized participants.			
Units: Subjects			
Argentina	32	30	23
Australia	16	21	19
Canada	26	44	24
Czechia	25	35	28
France	20	15	18
Germany	65	136	42
Hungary	23	27	20
Israel	12	15	15
Italy	7	5	5
Japan	39	86	37
Mexico	15	56	0
Poland	75	157	47
Russia	3	43	0
South Korea	24	68	13
Spain	24	22	24
Taiwan	9	44	0
United Kingdom	2	2	1
United States	110	214	73

Reporting group values	Total		
Number of subjects	1936		
Age categorical			
Units: Subjects			

Age continuous			
All randomized participants.			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	578		
Male	1358		
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	112		
Not Hispanic or Latino	282		
Unknown or Not Reported	1542		
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	65		
Asian	369		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	29		
White	1464		
More than one race	6		

Unknown or Not Reported	0		
Region of Enrollment			
All randomized participants.			
Units: Subjects			
Argentina	85		
Australia	56		
Canada	94		
Czechia	88		
France	53		
Germany	243		
Hungary	70		
Israel	42		
Italy	17		
Japan	162		
Mexico	71		
Poland	279		
Russia	46		
South Korea	105		
Spain	70		
Taiwan	53		
United Kingdom	5		
United States	397		

End points

End points reporting groups

Reporting group title	125 milligram (mg) Mirikizumab Q8W
Reporting group description:	
Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).	
Reporting group title	250 mg Mirikizumab Q8W Excluding Secukinumab
Reporting group description:	
Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).	
Reporting group title	Secukinumab/250 mg Mirikizumab Q8W
Reporting group description:	
Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.	
Reporting group title	125 milligram (mg) Mirikizumab Q8W Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	Secukinumab/250 mg Mirikizumab Q8W Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	

Primary: Percentage of Participants with a Static Physician’s Global Assessment Among Those who Entered the Study with a sPGA of 0,1

End point title	Percentage of Participants with a Static Physician’s Global Assessment Among Those who Entered the Study with a sPGA of 0,1[1]
End point description:	
The sPGA is the physician's determination of the participant's psoriasis (PsO) lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's PsO was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. Participants who did not meet the clinical response criteria or had missing data at Week 104 were considered non-responders for non-responder Imputation (NRI) analysis. Analysis population description (APD): All randomized participants who received at least one dose of drug and who entered Study AMAH with sPGA (0,1).	
End point type	Primary
End point timeframe:	
Week 104	
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: No inferential statistics was planned/conducted for this endpoint.	

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	467	820	296	
Units: percentage of participants				
number (confidence interval 95%)	46.7 (42.2 to 51.2)	55.7 (52.3 to 59.1)	38.9 (33.3 to 44.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants who Maintained a ≥90% Improvements in Psoriasis Area and Severity Index (PASI) 90 Among Those who Entered the Study with a PASI 90

End point title	Percentage of Participants who Maintained a ≥90% Improvements in Psoriasis Area and Severity Index (PASI) 90 Among Those who Entered the Study with a PASI 90[2]

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease). APD: All randomized participants who received at least one dose of drug and who entered AMAH with PASI 90 Response.

End point type	Primary

End point timeframe:

Week 104

Notes:

[2] - 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: No inferential statistics was planned/conducted for this endpoint.

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	460	813	302	
Units: percentage of participants				
number (confidence interval 95%)	49.3 (44.8 to 53.9)	56.8 (53.4 to 60.2)	39.4 (33.9 to 44.9)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease). APD: All randomized participants who received at least one dose of drug.

End point type	Secondary

End point timeframe:

Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	527	1020	389	
Units: percentage of participants				
number (confidence interval 95%)	30.4 (26.4 to 34.3)	36.4 (33.4 to 39.3)	22.6 (18.5 to 26.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 (free of itch, pain, stinging, and burning) in Those with a PSS Symptoms Score ≥1 at Baseline

End point title	Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 (free of itch, pain, stinging, and burning) in Those with a PSS Symptoms Score ≥1 at Baseline

End point description:

PSS is a patient-administered assessment of 4 symptoms (itch, pain, stinging, and burning); 3 signs (redness, scaling, and cracking); and 1 item on the discomfort related to symptoms/signs. The overall severity for each individual symptom/sign from the patient's psoriasis is indicated by selecting the number from a numeric rating scale (NRS) of 0 to 10 that best describes the worst level of each symptom/sign in the past 24 hours, where 0=no symptom/sign and 10=worst imaginable symptom/sign. In addition, a symptoms score ranging from 0 (no symptoms) to 40 (worst imaginable symptoms), and sign score of 0 (no signs) to 30 (worst imaginable signs) will be reported. APD: All randomized participants with PSS symptom score of ≥1 at baseline.

End point type	Secondary

End point timeframe:

Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	518	1008	376	
Units: percentage of participants				
number (confidence interval 95%)	31.1 (27.1 to 35.1)	33.6 (30.7 to 36.5)	23.4 (19.1 to 27.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Total Score of (0,1) With at Least a 5-Point Improvement (Reduction) From Baseline in Participants With a Baseline DLQI Total Score ≥5

End point title	Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Total Score of (0,1) With at Least a 5-Point Improvement (Reduction) From Baseline in Participants With a Baseline DLQI Total Score ≥5

End point description:

The DLQI is a patient-reported, 10-question, quality-of-life questionnaire that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Questions 3-10 also have an additional response category of "Not relevant" which is scored as "0". For all questions, if unanswered the question is scored as "0". Totals range from 0 to 30 (less to more impairment). A DLQI total score of 0 to 1 is considered as having no effect on a patient's health-related quality of life (HRQoL), and a 5-point change from baseline is considered as the minimal clinically important difference (MCID) threshold. APD: All randomized participants who had a baseline DLQI Total Score ≥5.

End point type	Secondary

End point timeframe:

Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	477	922	345	
Units: percentage of participants				
number (confidence interval 95%)	41.5 (37.1 to 45.9)	47.3 (44.1 to 50.5)	34.5 (29.5 to 39.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Psoriasis Scalp Severity Index (PSSI) Total Score in Participants with Scalp Involvement at Baseline

End point title	Change in Psoriasis Scalp Severity Index (PSSI) Total Score in Participants with Scalp Involvement at Baseline

End point description:

The PSSI is a physician assessment of erythema, induration and desquamation and percent of scalp that is covered with a scores range from 0 (none) to 4 (very severe). The composite score is derived from the sum of scores for erythema, induration, and desquamation multiplied by the score recorded for the extent of the scalp area involved, 1 (<10%) to 6 (90%-100%) with a total score ranging from 0 (less severity) to 72 (more severity). APD: All randomized participants who had Scalp Involvement at baseline.

End point type	Secondary

End point timeframe:

Baseline, Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	454	136	
Units: score on a scale				
arithmetic mean (standard deviation)	-20.9 (± 15.79)	-19.5 (± 13.48)	-19.6 (± 13.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Nail Psoriasis Severity Index (NAPSI) Total Score in Participants with Fingernail Involvement at Baseline

End point title	Change in Nail Psoriasis Severity Index (NAPSI) Total Score in Participants with Fingernail Involvement at Baseline

End point description:

The NAPSI scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix PsO by area of involvement. The fingernail is divided into quadrants. Each fingernail is given a score for fingernail bed PsO 0 (none) to 4 (PsO in 4 quadrants of the fingernail) and fingernail matrix PsO 0 (none) to 4 (Ps in 4 quadrants of the matrix), depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed or matrix PsO in each quadrant. The sum of all fingernails equals the total NAPSI score range is from 0 (no effect) to 80 (more severe psoriasis). APD: All randomized participants who had Nail Psoriasis involvement at baseline.

End point type	Secondary

End point timeframe:

Baseline, Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	136	304	89	
Units: score on a scale				
arithmetic mean (standard deviation)	-19.4 (± 17.75)	-21.0 (± 17.69)	-22.2 (± 18.75)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Palmoplantar Psoriasis Severity Index (PPASI) Total Score in Participants With Palmoplantar Involvement at Baseline

End point title	Change in Palmoplantar Psoriasis Severity Index (PPASI) Total Score in Participants With Palmoplantar Involvement at Baseline

End point description:

The PPASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 (no PPASI) to 72 (most severe PPASI). The PPASI was only assessed if participants have palmoplantar psoriasis at baseline. APD: All randomized participants who had palmoplantar involvement at baseline.

End point type	Secondary

End point timeframe:

Baseline, Week 104

End point values	125 milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	114	31	
Units: score on a scale				
arithmetic mean (standard deviation)	-6.55 (± 7.058)	-6.80 (± 8.391)	-7.38 (± 6.632)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment Period: Baseline Up To 208 Weeks, Follow-up Period: 0-12 Weeks

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	125 Milligram (mg) Mirikizumab Q8W

Reporting group description:

Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).

Reporting group title	250 mg Mirikizumab Q8W Excluding Secukinumab

Reporting group description:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

Reporting group title	Secukinumab/250 mg Mirikizumab Q8W

Reporting group description:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

Reporting group title	125 Milligram (mg) Mirikizumab Q8W Follow-up Period

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

Reporting group title	250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

Reporting group title	Secukinumab/250 mg Mirikizumab Q8W Follow-up Period

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

Serious adverse events	125 Milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	55 / 527 (10.44%)	88 / 1020 (8.63%)	35 / 389 (9.00%)
number of deaths (all causes)	2	6	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acute myeloid leukaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
adenocarcinoma of colon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
b-cell lymphoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
breast cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
colon cancer metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
gastric cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glioblastoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

growth hormone-producing pituitary tumour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma of bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
invasive lobular breast carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
lipoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
marginal zone lymphoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
non-small cell lung cancer stage iii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
prostate cancer recurrent			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 368 (0.00%)	0 / 711 (0.00%)	1 / 279 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinonasal papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of the oral cavity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
superficial spreading melanoma stage unspecified			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
thyroid cancer			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
Vascular disorders			
aortic aneurysm rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
embolism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
blepharoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
cholecystectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
coronary revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric polypectomy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hysterectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (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
percutaneous coronary intervention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stent placement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
stent removal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
gait disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
corneal graft rejection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
Reproductive system and breast disorders			
acquired phimosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (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
endometriosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[4]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
genital haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
haemorrhagic ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthmatic crisis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
dyspnoea exertional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypercapnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
respiratory failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
mental status changes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
Product issues			
device dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
Investigations			
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
ankle fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (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
cervical vertebral fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (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
closed globe injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
face injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
facial bones fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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

femoral neck fracture alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
foot fracture alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
graft complication alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
hand fracture alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament sprain alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
limb traumatic amputation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
lower limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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

neovaginal complication alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural complication alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary contusion alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
rib fracture alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
road traffic accident alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
scapula fracture alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
spinal compression fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
tendon injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
Congenital, familial and genetic disorders			
odontogenic cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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			
acute coronary syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	3 / 389 (0.77%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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 congestive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
cardiogenic shock			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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

coronary artery disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
ventricular tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
cerebral arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
cerebral venous sinus thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic inflammatory demyelinating polyradiculoneuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
essential tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
haemorrhage intracranial			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
ischaemic stroke			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
sedation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
sudden hearing loss			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
ocular hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
optic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulum			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
gastric ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
large intestine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
cholecystitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder fistula			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
drug eruption			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
primary hyperaldosteronism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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			
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
intervertebral disc disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (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
osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (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
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis perforated			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
bacteraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	8 / 1020 (0.78%)	2 / 389 (0.51%)
occurrences causally related to treatment / all	1 / 5	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
campylobacter colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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

campylobacter gastroenteritis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
diverticulitis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis viral alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
erysipelas alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (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
escherichia pyelonephritis alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
neutropenic sepsis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
osteomyelitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

postoperative wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (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
scrotal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (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
sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (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			
diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock hypoglycaemic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	125 Milligram (mg) Mirikizumab Q8W Follow-up Period	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W Follow-up

		Follow-up Period	Period
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 453 (1.55%)	6 / 861 (0.70%)	0 / 333 (0.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acute myeloid leukaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
adenocarcinoma of colon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
b-cell lymphoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer metastatic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric cancer			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glioblastoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
growth hormone-producing pituitary tumour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma of bone			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
invasive lobular breast carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lipoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
marginal zone lymphoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myelodysplastic syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-small cell lung cancer stage iii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer recurrent			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[1]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinonasal papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of the oral cavity			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
superficial spreading melanoma stage unspecified			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thyroid cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
aortic aneurysm rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
varicose vein			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
blepharoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystectomy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric polypectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
hysterectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[2]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
peripheral revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
stent placement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

stent removal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
death			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gait disturbance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
Immune system disorders			
corneal graft rejection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

acquired phimosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[3]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[4]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
genital haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[5]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[6]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
asthmatic crisis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea exertional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypercapnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
animal bite			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical vertebral fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
closed globe injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
face injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
graft complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb traumatic amputation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neovaginal complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[7]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
pulmonary contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

road traffic accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal compression fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
odontogenic cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
myocardial ischaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ventricular tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral venous sinus thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
cerebrovascular accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic inflammatory demyelinating polyradiculoneuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
essential tremor			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhage intracranial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sedation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
sudden hearing loss			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ocular hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
optic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
diverticulum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (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
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis chronic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
gallbladder fistula			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug eruption			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
primary hyperaldosteronism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis perforated			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bacteraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

campylobacter gastroenteritis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis viral alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia pyelonephritis alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic sepsis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (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

postoperative wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scrotal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[8]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
shock hypoglycaemic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Non-serious adverse events	125 Milligram (mg) Mirikizumab Q8W	250 mg Mirikizumab Q8W Excluding Secukinumab	Secukinumab/250 mg Mirikizumab Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	388 / 527 (73.62%)	756 / 1020 (74.12%)	288 / 389 (74.04%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acrochordon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
adenoma benign			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
anogenital warts			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
basal cell carcinoma			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
benign breast neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
benign hepatobiliary neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
benign vascular neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
bowen's disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
colon adenoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
dysplastic naevus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	2	3
fibroma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
fibrous histiocytoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
focal nodular hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
haemangioma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
lentigo maligna			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
lipoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
malignant ascites			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	1	4	1
meningioma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

neoplasm malignant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
pituitary tumour benign			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
prostate cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
pyogenic granuloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
seborrhoeic keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	4 / 389 (1.03%)
occurrences (all)	1	7	4
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[10]	3 / 159 (1.89%)	4 / 309 (1.29%)	0 / 110 (0.00%)
occurrences (all)	3	4	0
Vascular disorders			

aortic thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
deep vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
essential hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
flushing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
hot flush			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	22 / 527 (4.17%)	52 / 1020 (5.10%)	14 / 389 (3.60%)
occurrences (all)	22	54	15
hypertensive crisis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	3	2	1
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
jugular vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lymphoedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
lymphorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
orthostatic hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
peripheral artery occlusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
phlebitis superficial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

post thrombotic syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
varicose vein			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	5	0	0
white coat hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
acrochordon excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
ankle operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
appendicectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cardiac ablation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
cardioversion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
carpal tunnel decompression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	4	1
cataract operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	2	1	2
cholecystectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
circumcision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
corneal transplant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
coronary revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
dental care			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

dental implantation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	2	3	0
endodontic procedure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
endoscopic sleeve gastroplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
eyelid cyst removal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
finger amputation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
gastric bypass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
hernia hiatus repair			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hernia repair			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hysterectomy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[12]	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
internal fixation of fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
intra-uterine contraceptive device insertion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[13]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
intraocular lens implant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
knee arthroplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	3	1	0
knee operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
laparoscopic surgery			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
large intestinal polypectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	3	2	0
lens extraction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

lipolysis procedure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
lipoma excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
lithotripsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	3	0	0
nasal operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
open reduction of fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
papilloma excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	5 / 1020 (0.49%)	1 / 389 (0.26%)
occurrences (all)	1	6	1
peripheral nerve neurostimulation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
phlebectomy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
polypectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
pterygium operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
rhinoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
sinus operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
splint application			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
suture insertion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tenoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

tonsillectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tooth extraction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 527 (1.33%)	22 / 1020 (2.16%)	2 / 389 (0.51%)
occurrences (all)	9	23	2
tooth restoration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tumour excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
uterine dilation and curettage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[14]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
vasectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[15]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
vitrectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
wound drainage			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
adverse drug reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	3
asthenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	4 / 389 (1.03%)
occurrences (all)	2	1	4
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	3	3	0
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
fatigue			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	5 / 527 (0.95%)	10 / 1020 (0.98%)	3 / 389 (0.77%)
occurrences (all)	6	10	3
granuloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
hyperthermia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
implant site irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
influenza like illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	4 / 389 (1.03%)
occurrences (all)	3	5	6
injection site discolouration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
injection site bruising			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
injection site erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	8 / 1020 (0.78%)	3 / 389 (0.77%)
occurrences (all)	2	26	6
injection site haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	3

injection site induration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
injection site inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	3
injection site oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	5	2
injection site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 527 (1.52%)	22 / 1020 (2.16%)	6 / 389 (1.54%)
occurrences (all)	79	283	36
injection site rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
injection site pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	2 / 389 (0.51%)
occurrences (all)	1	12	3
injection site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	3	1
injection site reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	19 / 1020 (1.86%)	19 / 389 (4.88%)
occurrences (all)	15	108	44
lithiasis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
mucosal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	4	2	1
pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	3 / 389 (0.77%)
occurrences (all)	1	1	3
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	2	3	2
puncture site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	11 / 527 (2.09%)	17 / 1020 (1.67%)	11 / 389 (2.83%)
occurrences (all)	12	17	13
swelling face			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
temperature regulation disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tenderness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vaccination site joint pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
vaccination site oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
vaccination site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
vaccination site pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	12 / 1020 (1.18%)	2 / 389 (0.51%)
occurrences (all)	1	16	2
xerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
allergy to arthropod bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
anaphylactic reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
food allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hypersensitivity			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	9 / 1020 (0.88%)	3 / 389 (0.77%)
occurrences (all)	6	10	3
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[16]	2 / 159 (1.26%)	0 / 309 (0.00%)	0 / 110 (0.00%)
occurrences (all)	2	0	0
balanoposthitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[17]	1 / 368 (0.27%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	1	1	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[18]	3 / 368 (0.82%)	6 / 711 (0.84%)	2 / 279 (0.72%)
occurrences (all)	3	6	2
breast calcifications			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
breast cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
breast disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
breast mass			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
breast pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
cervical cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[19]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
dysmenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[20]	0 / 159 (0.00%)	3 / 309 (0.97%)	1 / 110 (0.91%)
occurrences (all)	0	12	1
endometrial thickening			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[21]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[22]	0 / 159 (0.00%)	1 / 309 (0.32%)	1 / 110 (0.91%)
occurrences (all)	0	1	1
erectile dysfunction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[23]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
genital erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
genital lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[24]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences (all)	0	0	1
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[25]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
menopausal symptoms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[26]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
menstruation irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[27]	1 / 159 (0.63%)	0 / 309 (0.00%)	0 / 110 (0.00%)
occurrences (all)	1	0	0
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[28]	1 / 159 (0.63%)	2 / 309 (0.65%)	2 / 110 (1.82%)
occurrences (all)	1	2	2
perineal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
perineal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[29]	1 / 159 (0.63%)	0 / 309 (0.00%)	0 / 110 (0.00%)
occurrences (all)	1	0	0
premenstrual pain			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[30]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
prostatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[31]	1 / 368 (0.27%)	0 / 711 (0.00%)	0 / 279 (0.00%)
occurrences (all)	1	0	0
pruritus genital			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
uterine cervical metaplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[32]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
vulval eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[33]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
vulvovaginal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[34]	1 / 159 (0.63%)	0 / 309 (0.00%)	0 / 110 (0.00%)
occurrences (all)	1	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[35]	1 / 159 (0.63%)	0 / 309 (0.00%)	0 / 110 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
allergic pharyngitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	5 / 1020 (0.49%)	0 / 389 (0.00%)
occurrences (all)	6	5	0
atelectasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
bronchitis chronic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
catarrh			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	0	4	0
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	16 / 527 (3.04%)	28 / 1020 (2.75%)	8 / 389 (2.06%)
occurrences (all)	16	30	8
cough variant asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
dysphonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

dyspnoea exertional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	7 / 1020 (0.69%)	2 / 389 (0.51%)
occurrences (all)	4	8	3
epistaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	3 / 389 (0.77%)
occurrences (all)	2	0	3
hiccups			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
hyperventilation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
laryngeal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	5	4	0
nasal oedema			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
nasal polyps			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
nasal turbinate abnormality			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
nasal ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	11 / 1020 (1.08%)	6 / 389 (1.54%)
occurrences (all)	5	12	6
paranasal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

pleural effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
productive cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
pulmonary hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
pulmonary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
pulmonary oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	15 / 1020 (1.47%)	2 / 389 (0.51%)
occurrences (all)	3	17	2
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	6 / 1020 (0.59%)	1 / 389 (0.26%)
occurrences (all)	4	8	1
sinonasal obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	1	6	1
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	6 / 1020 (0.59%)	2 / 389 (0.51%)
occurrences (all)	3	6	2
sneezing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
throat irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
vocal cord leukoplakia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
vocal cord polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
wheezing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
affective disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
alcohol abuse			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	11 / 1020 (1.08%)	7 / 389 (1.80%)
occurrences (all)	7	12	7
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
confusional state			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 527 (1.33%)	6 / 1020 (0.59%)	4 / 389 (1.03%)
occurrences (all)	7	6	4
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
distractibility			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

dysphoria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
initial insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	1	3
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	11 / 1020 (1.08%)	1 / 389 (0.26%)
occurrences (all)	4	11	1
major depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
mental fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
mental status changes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
panic attack			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
sleep disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	0 / 389 (0.00%)
occurrences (all)	1	7	0
stress			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
suicidal behaviour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
suicide attempt			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 527 (1.71%)	23 / 1020 (2.25%)	3 / 389 (0.77%)
occurrences (all)	10	28	3
arthroscopy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 527 (1.71%)	15 / 1020 (1.47%)	0 / 389 (0.00%)
occurrences (all)	11	22	0
aspiration joint			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
basophil count increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
bilirubin conjugated increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
biopsy lymph gland alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
biopsy skin alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
blood alkaline phosphatase increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	5	0
blood bilirubin increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
blood cholesterol increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
blood creatine phosphokinase increased alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	10 / 527 (1.90%)	20 / 1020 (1.96%)	7 / 389 (1.80%)
occurrences (all)	11	25	8

blood creatinine increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
blood gastrin increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
blood iron decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
blood parathyroid hormone increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
blood potassium increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
blood pressure abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
blood pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	2 / 389 (0.51%)
occurrences (all)	4	6	2
blood testosterone decreased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
blood triglycerides increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	9 / 1020 (0.88%)	2 / 389 (0.51%)
occurrences (all)	1	11	2
blood urea increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	3	5	1
body height decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
body temperature increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
bone scan			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cardiac murmur			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1

cardiac stress test			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
catheterisation cardiac			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
chest x-ray			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
colonoscopy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
colonoscopy normal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
computerised tomogram coronary artery			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
coronavirus test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
culture urine positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
echocardiogram			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ejection fraction decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
endoscopy upper gastrointestinal tract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 527 (1.71%)	21 / 1020 (2.06%)	2 / 389 (0.51%)
occurrences (all)	11	28	2
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
haematocrit increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
haemoglobin decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
haemoglobin increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
heart rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
heart rate increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
heart rate irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	10 / 1020 (0.98%)	3 / 389 (0.77%)
occurrences (all)	6	11	3
high density lipoprotein increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hormone level abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
influenza a virus test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
intraocular pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

kl-6 increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
liver function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
liver function test increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	3	4	1
lymphocyte count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lymphocyte count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
mammogram			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
neutrophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
platelet count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
platelet count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
podiatric examination normal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[36]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
protein urine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
renal function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	3 / 1020 (0.29%)	5 / 389 (1.29%)
occurrences (all)	3	3	5

serum ferritin decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
smear cervix			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[37]	0 / 159 (0.00%)	1 / 309 (0.32%)	0 / 110 (0.00%)
occurrences (all)	0	1	0
spermatozoa progressive motility abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[38]	0 / 368 (0.00%)	0 / 711 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	0	1
transaminases increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
ultrasound kidney			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ultrasound scan			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
urine leukocyte esterase			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
urine output decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vitamin d decreased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	3 / 389 (0.77%)
occurrences (all)	3	2	3
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	11 / 1020 (1.08%)	1 / 389 (0.26%)
occurrences (all)	2	11	1
white blood cell count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	3	0	0
Injury, poisoning and procedural complications			
abdominal injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
accidental overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
animal bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	1	1	2
animal scratch			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
arthropod bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	6 / 1020 (0.59%)	3 / 389 (0.77%)
occurrences (all)	4	8	3
arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	2	1	2
avulsion fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
back injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
bone contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
burns second degree			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1

cartilage injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
chest injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
chillblains			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	2	0	1
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	7 / 1020 (0.69%)	5 / 389 (1.29%)
occurrences (all)	4	7	6
corneal abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
epicondylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
eye injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	10 / 1020 (0.98%)	1 / 389 (0.26%)
occurrences (all)	3	11	1
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
foot fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	3	4	1
foreign body in eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
forearm fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
foreign body in throat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	3	1
heat stroke			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0

humerus fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	2
injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
joint injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	3	1
ligament rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	8 / 1020 (0.78%)	5 / 389 (1.29%)
occurrences (all)	0	8	5
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	15 / 1020 (1.47%)	3 / 389 (0.77%)
occurrences (all)	6	15	3
lower limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
meniscus injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	2 / 389 (0.51%)
occurrences (all)	1	2	2
muscle injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
muscle rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	1	2
muscle strain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	2 / 389 (0.51%)
occurrences (all)	3	4	2
post procedural haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
procedural nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1

procedural pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	9 / 1020 (0.88%)	2 / 389 (0.51%)
occurrences (all)	7	9	2
radius fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
retinal injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
rib fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
road traffic accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
scar			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	2	3	1
skin laceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	8 / 527 (1.52%)	5 / 1020 (0.49%)	4 / 389 (1.03%)
occurrences (all)	8	5	5
soft tissue injury			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
spinal column injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
synovial rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
tendon injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	0	4	1
thermal burn			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tooth fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	5 / 1020 (0.49%)	1 / 389 (0.26%)
occurrences (all)	1	5	1
upper limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	13 / 1020 (1.27%)	4 / 389 (1.03%)
occurrences (all)	3	13	5

vascular pseudoaneurysm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
wound complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
wound			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
Congenital, familial and genetic disorders			
atrial septal defect			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
block vertebra			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
dermoid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	2
hydrocele			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[39]	0 / 368 (0.00%)	1 / 711 (0.14%)	0 / 279 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			

angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	3	2	0
angina unstable			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
aortic valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
aortic valve sclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
arrhythmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	5	3	2
atrioventricular block first degree			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
bundle branch block left			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
cardiac failure congestive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
cardiomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cardiomyopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
cardiovascular disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
coronary artery disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
coronary artery stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
coronary artery thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

coronary ostial stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
left atrial enlargement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
left ventricular failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
left ventricular hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
mitral valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
myocardial ischaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
palpitations			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	2	3	0
pericarditis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
right atrial enlargement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
right ventricular hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
sinus tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	0	3	2
tricuspid valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
Nervous system disorders			
amnesia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
anosmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
arachnoid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ataxia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
bell's palsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
carotid arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	6	0

cerebrovascular accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cervical radiculopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
cognitive disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
complex regional pain syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
cubital tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
diabetic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	9 / 1020 (0.88%)	0 / 389 (0.00%)
occurrences (all)	4	9	0
facial paralysis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	18 / 527 (3.42%)	55 / 1020 (5.39%)	21 / 389 (5.40%)
occurrences (all)	21	93	32
hemianopia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
hemiparesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
lethargy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
loss of consciousness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1

lumbar radiculopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
memory impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	1 / 389 (0.26%)
occurrences (all)	1	6	1
myelopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
nerve compression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	3	1
neuropathy peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	2	5	0
peripheral nerve lesion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
peroneal nerve palsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
pineal gland cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	9 / 1020 (0.88%)	3 / 389 (0.77%)
occurrences (all)	2	11	3
seizure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
somnolence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
syncope			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1

transient aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	14 / 1020 (1.37%)	2 / 389 (0.51%)
occurrences (all)	4	16	2
anaemia macrocytic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
anaemia of chronic disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
bone marrow oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
eosinophilia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
febrile neutropenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hypercoagulation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	2	0	1
leukocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
leukopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	3 / 389 (0.77%)
occurrences (all)	0	2	3
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	3	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
macrocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
neutropenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	3 / 389 (0.77%)
occurrences (all)	0	1	3

neutrophilia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
pancytopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
splenomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
thrombocytopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	5 / 1020 (0.49%)	0 / 389 (0.00%)
occurrences (all)	1	5	0
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
cerumen impaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
deafness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
deafness neurosensory			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
deafness unilateral			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	2 / 389 (0.51%)
occurrences (all)	0	2	2
eustachian tube dysfunction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
eustachian tube obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
external ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hypoacusis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	2
inner ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

middle ear effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	3	4	0
tympanic membrane perforation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	6 / 1020 (0.59%)	3 / 389 (0.77%)
occurrences (all)	3	7	3
vertigo positional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
arteriosclerotic retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
blepharospasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	2	4	2
chalazion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
chorioretinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
conjunctival hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	2 / 389 (0.51%)
occurrences (all)	3	2	2
diabetic retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	2	3	0
eye allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

eye disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
eye pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
eyelid thickening			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
glaucoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	3	0	0
iridocyclitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lacrimation increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
macular degeneration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ocular surface disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
open angle glaucoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
optic disc drusen			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
optic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	2
trichiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
ulcerative keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vision blurred			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	2	2	0
vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1

vitreous haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
vitreous prolapse			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	3	1
abdominal distension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
abdominal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	13 / 1020 (1.27%)	5 / 389 (1.29%)
occurrences (all)	2	15	17
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	9 / 1020 (0.88%)	6 / 389 (1.54%)
occurrences (all)	4	10	6
angular cheilitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
anorectal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
chronic gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
constipation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	9 / 1020 (0.88%)	4 / 389 (1.03%)
occurrences (all)	2	9	5
dental caries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	12 / 1020 (1.18%)	2 / 389 (0.51%)
occurrences (all)	3	13	2
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	15 / 527 (2.85%)	20 / 1020 (1.96%)	9 / 389 (2.31%)
occurrences (all)	15	21	33
dry mouth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

duodenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	6 / 1020 (0.59%)	5 / 389 (1.29%)
occurrences (all)	3	9	16
dysphagia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
enteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
enterocolitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
epiploic appendagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
food poisoning			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	1	3	1
gastric polyps			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
gastric ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	8 / 1020 (0.78%)	2 / 389 (0.51%)
occurrences (all)	4	10	2
gastritis erosive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
gastrointestinal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	8 / 1020 (0.78%)	3 / 389 (0.77%)
occurrences (all)	5	9	3
gingival pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
glossitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

haematochezia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
haemorrhagic erosive gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	3 / 389 (0.77%)
occurrences (all)	1	3	3
hiatus hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hyperaesthesia teeth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ileus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
inguinal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	3 / 389 (0.77%)
occurrences (all)	2	1	3
intra-abdominal haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
large intestine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
lip swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
lip erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lumbar hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
melaena			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
mouth ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	12 / 1020 (1.18%)	1 / 389 (0.26%)
occurrences (all)	4	19	1
noninfective sialoadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

odynophagia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
oesophageal obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
oesophagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
oral hyperkeratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
oral lichen planus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
oral papule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
pancreatic disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
periodontal disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	6 / 1020 (0.59%)	1 / 389 (0.26%)
occurrences (all)	0	6	1
proctitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
rectal polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
terminal ileitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
tooth disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
tooth impacted			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	16 / 1020 (1.57%)	9 / 389 (2.31%)
occurrences (all)	5	19	9
umbilical hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	5 / 1020 (0.49%)	1 / 389 (0.26%)
occurrences (all)	5	5	1

Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
cholangitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cholecystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	8 / 1020 (0.78%)	2 / 389 (0.51%)
occurrences (all)	1	8	2
fatty liver alcoholic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
gallbladder polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	3 / 389 (0.77%)
occurrences (all)	0	0	3
hepatic cirrhosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hepatic cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
hepatic function abnormal			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	3	4	0
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	12 / 1020 (1.18%)	2 / 389 (0.51%)
occurrences (all)	5	12	2
hepatitis alcoholic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hepatomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
liver disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
nonalcoholic fatty liver disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
primary biliary cholangitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
acanthosis nigricans			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	6 / 1020 (0.59%)	4 / 389 (1.03%)
occurrences (all)	4	6	4
acne varioliformis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
actinic keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	5 / 1020 (0.49%)	2 / 389 (0.51%)
occurrences (all)	2	5	2
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
angioedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	2
asteatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
dermal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	2	4	0

dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	1	3	1
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	10 / 1020 (0.98%)	5 / 389 (1.29%)
occurrences (all)	4	12	8
dermatitis papillaris capillitii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
diabetic foot			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
drug eruption			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	1	0	2
dry skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	1	3	3
dyshidrotic eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	1	4	1
eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	10 / 1020 (0.98%)	3 / 389 (0.77%)
occurrences (all)	4	10	3
eczema asteatotic			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	2	1	2
eczema nummular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
hand dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
hyperkeratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
ingrowing nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	2	0	1
intertrigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	3	5	1
itching scar			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0

lichen planus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lichen sclerosus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lichenification			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lichenoid keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
mechanical urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
milia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
miliaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	3
nail discolouration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
nail dystrophy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
neurodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
onycholysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
palmar erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
papule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	2
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
prurigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1

pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	12 / 527 (2.28%)	17 / 1020 (1.67%)	6 / 389 (1.54%)
occurrences (all)	12	20	7
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	5 / 1020 (0.49%)	2 / 389 (0.51%)
occurrences (all)	3	5	2
rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
skin burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
skin erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
skin exfoliation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
skin fissures			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	1	2
skin lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
skin tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
skin plaque			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
skin ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
stasis dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
urticaria physical			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	12 / 1020 (1.18%)	1 / 389 (0.26%)
occurrences (all)	5	12	1
vitiligo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
cystitis noninfective			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	2	1	0
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
glycosuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	2	3	1
haemorrhage urinary tract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hydronephrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
ketonuria			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
kidney congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
leukocyturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
nephritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	5 / 1020 (0.49%)	0 / 389 (0.00%)
occurrences (all)	3	8	0
nocturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
pollakiuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
proteinuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	4	0

renal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	3 / 389 (0.77%)
occurrences (all)	2	3	3
renal failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
renal impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
Endocrine disorders			
acromegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
goitre			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hyperparathyroidism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hyperprolactinaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
hyperthyroidism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	1	2
hypogonadism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
hypothyroidism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	6 / 1020 (0.59%)	1 / 389 (0.26%)
occurrences (all)	4	6	1
thyroid mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	30 / 527 (5.69%)	87 / 1020 (8.53%)	19 / 389 (4.88%)
occurrences (all)	36	95	23
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	10 / 1020 (0.98%)	2 / 389 (0.51%)
occurrences (all)	3	10	2
arthropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
axillary mass			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	25 / 527 (4.74%)	48 / 1020 (4.71%)	20 / 389 (5.14%)
occurrences (all)	27	61	22
bursitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	6 / 1020 (0.59%)	0 / 389 (0.00%)
occurrences (all)	4	6	0
cervical spinal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
chondrocalcinosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
chondropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
dactylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	5	1	2
enthesopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	4	0

exostosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
fibromyalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	2	0	1
groin pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
haemarthrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
intervertebral disc degeneration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
intervertebral disc disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	7 / 1020 (0.69%)	2 / 389 (0.51%)
occurrences (all)	3	7	2
intervertebral disc space narrowing			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
joint effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
joint stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
joint swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
ligament disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
ligament pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
muscle contracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	9 / 1020 (0.88%)	0 / 389 (0.00%)
occurrences (all)	1	10	0

muscle tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	0	4	1
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	12 / 1020 (1.18%)	3 / 389 (0.77%)
occurrences (all)	7	16	3
musculoskeletal stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
myositis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
neck pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	9 / 1020 (0.88%)	2 / 389 (0.51%)
occurrences (all)	2	9	3
osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	8 / 1020 (0.78%)	4 / 389 (1.03%)
occurrences (all)	7	8	4
osteopenia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
osteoporosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	22 / 1020 (2.16%)	7 / 389 (1.80%)
occurrences (all)	7	28	8
pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
patellofemoral pain syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
periarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	4	0
plantar fasciitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	3	2	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 527 (1.71%)	12 / 1020 (1.18%)	10 / 389 (2.57%)
occurrences (all)	9	12	12
rheumatic disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

rotator cuff syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	2 / 389 (0.51%)
occurrences (all)	1	4	2
sacroiliitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
scoliosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	7 / 1020 (0.69%)	2 / 389 (0.51%)
occurrences (all)	0	7	2
spinal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	7 / 1020 (0.69%)	1 / 389 (0.26%)
occurrences (all)	6	11	1
spinal retrolisthesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
spondylolisthesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
synovial cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
synovitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	5	3	1
tendon disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	10 / 1020 (0.98%)	4 / 389 (1.03%)
occurrences (all)	1	10	4
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	2	3	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
trigger finger			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
abdominal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
abscess			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
abscess jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	3	3	0
acute sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	1	6	0
adenoviral conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
appendicitis perforated			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
asymptomatic covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0

bacterial vaginosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[40]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences (all)	0	0	1
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	1	1	1
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	10 / 527 (1.90%)	24 / 1020 (2.35%)	4 / 389 (1.03%)
occurrences (all)	11	25	4
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	33 / 527 (6.26%)	66 / 1020 (6.47%)	26 / 389 (6.68%)
occurrences (all)	33	67	28
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
candida infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	2	0	0
cellulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	2 / 389 (0.51%)
occurrences (all)	1	6	2
chronic sinusitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	8 / 1020 (0.78%)	2 / 389 (0.51%)
occurrences (all)	4	8	2
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
conjunctivitis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
coronavirus infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
coronavirus pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	7 / 1020 (0.69%)	2 / 389 (0.51%)
occurrences (all)	4	8	2
cystitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	3 / 389 (0.77%)
occurrences (all)	0	2	4
ear infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
endocarditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
enterococcal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
epididymitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[41]	0 / 368 (0.00%)	3 / 711 (0.42%)	0 / 279 (0.00%)
occurrences (all)	0	3	0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	2	2	1
erythema migrans			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
erythrasma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
folliculitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	7 / 527 (1.33%)	6 / 1020 (0.59%)	3 / 389 (0.77%)
occurrences (all)	7	6	3
fungal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
fungal skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
furuncle			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	4 / 389 (1.03%)
occurrences (all)	1	8	6
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	15 / 1020 (1.47%)	3 / 389 (0.77%)
occurrences (all)	6	17	3
gastroenteritis norovirus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
gastroenteritis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
gastroenteritis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	6 / 1020 (0.59%)	1 / 389 (0.26%)
occurrences (all)	1	6	1
gastrointestinal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	5 / 1020 (0.49%)	0 / 389 (0.00%)
occurrences (all)	2	5	0

gastrointestinal viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
genital candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0
genital herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	3
genital herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
genital infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
gingivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	5 / 1020 (0.49%)	1 / 389 (0.26%)
occurrences (all)	3	5	1
helicobacter infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	2	2	0
hepatitis a			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
herpangina			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	4	0
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	6 / 527 (1.14%)	7 / 1020 (0.69%)	4 / 389 (1.03%)
occurrences (all)	6	8	4
herpes zoster infection neurological			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
histoplasmosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	2	3	1
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	0	2	1
infected cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	18 / 1020 (1.76%)	2 / 389 (0.51%)
occurrences (all)	4	18	2

injection site infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
intervertebral discitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
laryngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	2 / 389 (0.51%)
occurrences (all)	0	2	2
latent tuberculosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	4 / 1020 (0.39%)	4 / 389 (1.03%)
occurrences (all)	4	4	4
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	0	1	2
lyme disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
lymphogranuloma venereum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
molluscum contagiosum			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
mucocutaneous candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
mycobacterial infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
myringitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	55 / 527 (10.44%)	157 / 1020 (15.39%)	43 / 389 (11.05%)
occurrences (all)	69	226	57
onychomycosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	2 / 389 (0.51%)
occurrences (all)	2	1	2
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
oral candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	0	4	0
oral fungal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 527 (1.33%)	11 / 1020 (1.08%)	2 / 389 (0.51%)
occurrences (all)	9	12	2
oral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
oropharyngeal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
otitis media			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	5 / 1020 (0.49%)	2 / 389 (0.51%)
occurrences (all)	1	5	2
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	3	4	0
papilloma viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
paronychia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
parotitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
pericoronitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
perineal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
periodontitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	2 / 389 (0.51%)
occurrences (all)	0	4	2
pharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	9 / 527 (1.71%)	17 / 1020 (1.67%)	10 / 389 (2.57%)
occurrences (all)	11	19	10
pharyngitis streptococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	2	4	1
pharyngotonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	5 / 1020 (0.49%)	0 / 389 (0.00%)
occurrences (all)	0	5	0
pilonidal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	1 / 389 (0.26%)
occurrences (all)	1	3	1
post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0

postoperative wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	1	0	1
pulpitis dental			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	3 / 1020 (0.29%)	2 / 389 (0.51%)
occurrences (all)	3	5	2
rash pustular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	8 / 1020 (0.78%)	4 / 389 (1.03%)
occurrences (all)	4	9	4
respiratory tract infection viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	11 / 1020 (1.08%)	3 / 389 (0.77%)
occurrences (all)	5	12	3
rhinovirus infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
root canal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
salmonellosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	1 / 389 (0.26%)
occurrences (all)	0	1	1
sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	7 / 527 (1.33%)	21 / 1020 (2.06%)	7 / 389 (1.80%)
occurrences (all)	8	23	8
skin candida			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	3	0
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
soft tissue infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
subcutaneous abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
superinfection mycobacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
superinfection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
suspected covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	1	3	0

testicular abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[42]	1 / 368 (0.27%)	0 / 711 (0.00%)	0 / 279 (0.00%)
occurrences (all)	1	0	0
tinea cruris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	3	1	0
tinea infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	3	1	0
tinea pedis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	12 / 1020 (1.18%)	4 / 389 (1.03%)
occurrences (all)	8	13	4
tinea versicolour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	7 / 1020 (0.69%)	1 / 389 (0.26%)
occurrences (all)	6	9	1
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	10 / 1020 (0.98%)	5 / 389 (1.29%)
occurrences (all)	5	10	5
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	3	4	1
tooth infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	10 / 1020 (0.98%)	4 / 389 (1.03%)
occurrences (all)	5	11	4
trichophytosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
tuberculosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	22 / 527 (4.17%)	54 / 1020 (5.29%)	29 / 389 (7.46%)
occurrences (all)	29	64	42
urethritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	11 / 527 (2.09%)	30 / 1020 (2.94%)	9 / 389 (2.31%)
occurrences (all)	14	38	9
urinary tract infection enterococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vaginal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[43]	1 / 159 (0.63%)	3 / 309 (0.97%)	0 / 110 (0.00%)
occurrences (all)	1	8	0
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
viral sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0

viral upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	4 / 1020 (0.39%)	2 / 389 (0.51%)
occurrences (all)	2	4	2
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[44]	1 / 159 (0.63%)	2 / 309 (0.65%)	1 / 110 (0.91%)
occurrences (all)	1	4	1
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[45]	3 / 159 (1.89%)	1 / 309 (0.32%)	2 / 110 (1.82%)
occurrences (all)	3	1	2
vulvovaginitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[46]	0 / 159 (0.00%)	0 / 309 (0.00%)	1 / 110 (0.91%)
occurrences (all)	0	0	1
wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	2 / 389 (0.51%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
abnormal weight gain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	1 / 389 (0.26%)
occurrences (all)	0	4	1
diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	12 / 1020 (1.18%)	2 / 389 (0.51%)
occurrences (all)	5	13	2
dyslipidaemia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	4 / 527 (0.76%)	5 / 1020 (0.49%)	3 / 389 (0.77%)
occurrences (all)	4	5	3
glucose tolerance impaired			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	1	1	0
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	9 / 1020 (0.88%)	3 / 389 (0.77%)
occurrences (all)	3	13	4
hypercalcaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	4 / 527 (0.76%)	12 / 1020 (1.18%)	3 / 389 (0.77%)
occurrences (all)	4	14	3
hyperglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 527 (0.38%)	10 / 1020 (0.98%)	2 / 389 (0.51%)
occurrences (all)	2	10	2
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	1 / 389 (0.26%)
occurrences (all)	1	2	1
hyperlipidaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	11 / 1020 (1.08%)	0 / 389 (0.00%)
occurrences (all)	3	11	0
hypernatraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	0	0	0

hypertriglyceridaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	17 / 1020 (1.67%)	0 / 389 (0.00%)
occurrences (all)	0	28	0
hyperuricaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	5 / 1020 (0.49%)	1 / 389 (0.26%)
occurrences (all)	5	6	1
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	1	2	0
hypomagnesaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	2 / 1020 (0.20%)	0 / 389 (0.00%)
occurrences (all)	0	2	0
hyponatraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	3 / 1020 (0.29%)	0 / 389 (0.00%)
occurrences (all)	0	3	0
hypovitaminosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
impaired fasting glucose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
insulin resistance			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 527 (0.19%)	0 / 1020 (0.00%)	0 / 389 (0.00%)
occurrences (all)	1	0	0
iron deficiency			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 527 (0.00%)	0 / 1020 (0.00%)	1 / 389 (0.26%)
occurrences (all)	0	0	1
overweight			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 527 (0.95%)	8 / 1020 (0.78%)	5 / 389 (1.29%)
occurrences (all)	5	8	5
underweight			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	1 / 1020 (0.10%)	0 / 389 (0.00%)
occurrences (all)	0	1	0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 527 (0.00%)	4 / 1020 (0.39%)	0 / 389 (0.00%)
occurrences (all)	0	4	0
vitamin d deficiency			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	3 / 527 (0.57%)	5 / 1020 (0.49%)	2 / 389 (0.51%)
occurrences (all)	3	5	2

Non-serious adverse events	125 Milligram (mg) Mirikizumab Q8W Follow-up Period	250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period	Secukinumab/250 mg Mirikizumab Q8W Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	70 / 453 (15.45%)	120 / 861 (13.94%)	47 / 333 (14.11%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acrochordon			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
adenoma benign			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anogenital warts			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
benign breast neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
benign hepatobiliary neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
benign vascular neoplasm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bowen's disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
colon adenoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0

dysplastic naevus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fibroma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fibrous histiocytoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
focal nodular hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
haemangioma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
malignant ascites			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
meningioma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neoplasm malignant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pituitary tumour benign			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[9]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
pyogenic granuloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

uterine leiomyoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[10]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
aortic thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
flushing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	3 / 861 (0.35%)	0 / 333 (0.00%)
occurrences (all)	0	3	0
hypertensive crisis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
jugular vein thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphoedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
peripheral artery occlusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

phlebitis superficial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
post thrombotic syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
acrochordon excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ankle operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
appendicectomy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiac ablation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardioversion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
carpal tunnel decompression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cataract operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	2	0	0
cholecystectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
circumcision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[11]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
corneal transplant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronary revascularisation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

dental care			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
dental implantation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
endodontic procedure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
endoscopic sleeve gastroplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eyelid cyst removal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
finger amputation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastric bypass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hernia hiatus repair			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hysterectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[12]	0 / 130 (0.00%)	1 / 259 (0.39%)	0 / 89 (0.00%)
occurrences (all)	0	1	0
internal fixation of fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intra-uterine contraceptive device insertion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[13]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
intraocular lens implant			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
knee arthroplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
knee operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
laparoscopic surgery			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
large intestinal polypectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0

lens extraction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lipolysis procedure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lithotripsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
open reduction of fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
papilloma excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
peripheral nerve neurostimulation			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
polypectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pterygium operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rhinoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sinus operation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
splint application			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
suture insertion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

tenoplasty			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tonsillectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
tooth extraction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
tooth restoration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tumour excision			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
uterine dilation and curettage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[14]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[15]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
vitrectomy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
wound drainage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
adverse drug reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
asthenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chest discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
effusion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	2 / 333 (0.60%)
occurrences (all)	0	0	2
granuloma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
implant site irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
injection site discolouration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site bruising			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

injection site haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
injection site reaction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
lithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
mucosal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nodule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

puncture site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 453 (1.10%)	2 / 861 (0.23%)	1 / 333 (0.30%)
occurrences (all)	5	2	1
swelling face			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
temperature regulation disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vaccination site joint pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vaccination site oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vaccination site swelling			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
vaccination site pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
xerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
allergy to arthropod bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
allergy to arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anaphylactic reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
food allergy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[16]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[17]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[18]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
breast calcifications			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
breast cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
breast disorder			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cervical cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[19]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[20]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
endometrial thickening			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[21]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
endometriosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[22]	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[23]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
genital erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

genital lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
heavy menstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[24]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
intermenstrual bleeding			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[25]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
menopausal symptoms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[26]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[27]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[28]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
perineal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
perineal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
polycystic ovaries			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed[29]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
premenstrual pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[30]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[31]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
uterine cervical metaplasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[32]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vulval eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[33]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vulvovaginal inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[34]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[35]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
allergic pharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
atelectasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bronchitis chronic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
catarrh			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	1	2	0
cough variant asthma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

dysphonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dyspnoea exertional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
epistaxis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hiccups			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
hyperventilation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
laryngeal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal turbinate abnormality			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal turbinate hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasal ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	1 / 333 (0.30%)
occurrences (all)	0	2	1
paranasal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

paranasal sinus discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pulmonary hypertension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pulmonary oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
rhinorrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
sinonasal obstruction			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
throat irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vocal cord leukoplakia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vocal cord polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
wheezing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
affective disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
alcohol abuse			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
distractibility			

alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dysphoria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
initial insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
major depression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mental fatigue			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mental status changes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mood swings			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
suicidal ideation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
suicidal behaviour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
suicide attempt			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
arthroscopy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
aspiration joint			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
basophil count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bilirubin conjugated increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
biopsy lymph gland			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
biopsy skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	2 / 333 (0.60%)
occurrences (all)	1	0	2
blood creatinine increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood gastrin increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
blood iron decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood parathyroid hormone increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood potassium increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood pressure abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood testosterone decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
blood urea increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
body height decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
body temperature increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bone scan			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

cardiac murmur			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiac stress test			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
catheterisation cardiac			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chest x-ray			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
colonoscopy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
colonoscopy normal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
computerised tomogram coronary artery			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronavirus test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
culture urine positive			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
echocardiogram			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ejection fraction decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
endoscopy upper gastrointestinal tract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haematocrit increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haemoglobin decreased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haemoglobin increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
heart rate decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
heart rate irregular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
high density lipoprotein increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hormone level abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
influenza a virus test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

intraocular pressure increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
kl-6 increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphocyte count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mammogram			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
platelet count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
podiatric examination normal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[36]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
protein urine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
red blood cell count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
renal function test abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1

sars-cov-2 test positive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
serum ferritin decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
smear cervix			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[37]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
spermatozoa progressive motility abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[38]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ultrasound kidney			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ultrasound scan			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
urine leukocyte esterase			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
urine output decreased			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
white blood cell count increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
abdominal injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
accidental overdose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
animal bite			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
animal scratch			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
arthropod sting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
avulsion fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
back injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bone contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

burns second degree			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cartilage injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chest injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chillblains			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
clavicle fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	1 / 333 (0.30%)
occurrences (all)	1	1	1
corneal abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
fibula fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
foreign body in eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
forearm fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
foreign body in throat			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1

heat stroke			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ligament rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
ligament sprain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	1	0	2
lower limb fracture			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
post procedural haematoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

procedural nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 453 (0.44%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	2	0	0
radius fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
retinal injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
road traffic accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
scar			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
soft tissue injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
spinal column injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
synovial rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

vaccination complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	2 / 333 (0.60%)
occurrences (all)	1	1	3
vascular pseudoaneurysm			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
wound complication			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
atrial septal defect			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
block vertebra			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dermoid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hydrocele			
alternative dictionary used:			

MedDRA 24.1			
subjects affected / exposed[39]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
angina unstable			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
aortic valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
aortic valve sclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
arrhythmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
atrioventricular block first degree			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bradycardia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bundle branch block left			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiac failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiac failure congestive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiomyopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cardiovascular disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronary artery disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronary artery stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1

coronary artery thrombosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronary ostial stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
left atrial enlargement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
left ventricular failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
left ventricular hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mitral valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
myocardial ischaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pericarditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
right atrial enlargement			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
right ventricular hypertrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tricuspid valve incompetence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
amnesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anosmia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
arachnoid cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ataxia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bell's palsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
carotid arteriosclerosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cerebrovascular accident			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cervical radiculopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cognitive disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
complex regional pain syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
cubital tunnel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
diabetic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0

facial paralysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 453 (0.44%)	7 / 861 (0.81%)	2 / 333 (0.60%)
occurrences (all)	2	7	2
hemianopia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hemiparesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lethargy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
loss of consciousness			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lumbar radiculopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
memory impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
myelopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nerve compression			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neuropathy peripheral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

peripheral nerve lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
peroneal nerve palsy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pineal gland cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	1	0	1
seizure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
syncope			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
transient aphasia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
anaemia macrocytic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anaemia of chronic disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bone marrow oedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
febrile neutropenia			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypercoagulation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	1 / 333 (0.30%)
occurrences (all)	0	1	1
lymphadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
macrocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

neutropenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
neutrophilia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pancytopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
splenomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
cerumen impaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
deafness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
deafness neurosensory			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
deafness unilateral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
ear pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eustachian tube dysfunction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eustachian tube obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
external ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

inner ear inflammation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
middle ear effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tympanic membrane perforation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vertigo positional			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
arteriosclerotic retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blepharitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
blepharospasm			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
cataract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chalazion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chorioretinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctival hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
diabetic retinopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

eye allergy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eye disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eyelid thickening			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
glaucoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
iridocyclitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
macular degeneration			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ocular surface disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
open angle glaucoma			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
optic disc drusen			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
optic neuropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
trichiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ulcerative keratitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

vitreous detachment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitreous haemorrhage			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitreous prolapse			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abdominal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
angular cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
anorectal discomfort			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cheilitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
colitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
dental caries			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	1 / 333 (0.30%)
occurrences (all)	0	1	1
diarrhoea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	3 / 861 (0.35%)	2 / 333 (0.60%)
occurrences (all)	1	3	2

dry mouth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
enterocolitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
epiploic appendagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastric ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
gastritis erosive			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastrointestinal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gingival pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

glossitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haemorrhagic erosive gastritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
hiatus hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperaesthesia teeth			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ileus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intra-abdominal haematoma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
lip swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lip erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
melaena			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	2 / 453 (0.44%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	2	1	0

noninfective sialoadenitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
odynophagia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	1	0	1
oesophageal obstruction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oral hyperkeratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oral lichen planus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oral papule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
pancreatic disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
proctitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rectal polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
terminal ileitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
tooth disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tooth impacted			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
umbilical hernia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

vomiting			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
cholangitis acute			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cholecystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fatty liver alcoholic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gallbladder polyp			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatic cirrhosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatic cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatitis alcoholic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatomegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
liver disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nonalcoholic fatty liver disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
primary biliary cholangitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
acanthosis nigricans			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
acne varioliformis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
asteatosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
dermatitis contact			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dermatitis papillaris capillitii			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
diabetic foot			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
drug eruption			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0

eczema asteatotic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
eczema nummular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperkeratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ingrowing nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
itching scar			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
lichen planus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lichenification			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lichenoid keratosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mechanical urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nail discolouration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

nail dystrophy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neurodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
night sweats			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
palmar erythema			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
prurigo			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
psoriasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
skin burning sensation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin erosion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin exfoliation			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

skin fissures			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin lesion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin plaque			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
stasis dermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
urticaria physical			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitiligo			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chronic kidney disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cystitis noninfective			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
glycosuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
haematuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
haemorrhage urinary tract			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hydronephrosis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ketonuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
kidney congestion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
leukocyturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nephritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nocturia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
proteinuria			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0

renal colic			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
renal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
renal failure			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
renal impairment			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
ureterolithiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
acromegaly			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
autoimmune thyroiditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
hyperparathyroidism			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperprolactinaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperthyroidism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypogonadism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
thyroid mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	2 / 333 (0.60%)
occurrences (all)	0	1	2
arthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
arthropathy			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
axillary mass			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	4 / 861 (0.46%)	0 / 333 (0.00%)
occurrences (all)	0	4	0
bursitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cervical spinal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
chondropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
dactylitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

enthesopathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fibromyalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
haemarthrosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intervertebral disc disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
intervertebral disc space narrowing			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
joint effusion			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
joint stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ligament disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ligament pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

muscle spasms			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
myositis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
osteopenia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
osteoporosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
pain in jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
patellofemoral pain syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
periarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

rheumatic disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
sacroiliitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
scoliosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
spinal retrolisthesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
spondylolisthesis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tendon disorder			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal infection			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abscess jaw			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
acute sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
adenoviral conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
appendicitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
appendicitis perforated			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0

asymptomatic covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[40]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	1	2	0
bronchitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	16 / 453 (3.53%)	11 / 861 (1.28%)	6 / 333 (1.80%)
occurrences (all)	16	11	6
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
candida infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
chronic sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
conjunctivitis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronavirus infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
coronavirus pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
cystitis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

dermatophytosis of nail			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
endocarditis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
enterococcal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[41]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	1 / 333 (0.30%)
occurrences (all)	0	1	1
fungal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
furuncle			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
gastroenteritis norovirus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastroenteritis bacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

gastrointestinal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gastrointestinal viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
genital herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
genital infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
herpangina			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
herpes zoster infection neurological			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
histoplasmosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
impetigo			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
infected cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

influenza			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	1	0	1
injection site infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
intervertebral discitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
latent tuberculosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lyme disease			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
lymphogranuloma venereum			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mucocutaneous candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
mycobacterial infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 453 (1.10%)	11 / 861 (1.28%)	5 / 333 (1.50%)
occurrences (all)	5	11	5
onychomycosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oral candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

oral fungal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	1	2	0
oral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
oropharyngeal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
otitis externa			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
papilloma viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
parotitis			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pericoronitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
perineal abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
pilonidal cyst			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0

post procedural infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rash pustular			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
rhinovirus infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
root canal infection			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
salmonellosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	2 / 333 (0.60%)
occurrences (all)	1	0	2
skin candida			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
skin infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
soft tissue infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
superinfection mycobacterial			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
superinfection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

suspected covid-19			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
testicular abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[42]	0 / 323 (0.00%)	0 / 602 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
tinea versicolour			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
tooth infection			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
trichophytosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
tuberculosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	5 / 453 (1.10%)	5 / 861 (0.58%)	4 / 333 (1.20%)
occurrences (all)	5	5	4
urethritis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
urinary tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	5 / 861 (0.58%)	1 / 333 (0.30%)
occurrences (all)	0	6	1
urinary tract infection enterococcal			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[43]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

viral sinusitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	0	2	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[44]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[45]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed[46]	0 / 130 (0.00%)	0 / 259 (0.00%)	0 / 89 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
abnormal weight gain			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	2 / 333 (0.60%)
occurrences (all)	1	0	2
dyslipidaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	1	1	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
hypercalcaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hyperkalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
hyperlipidaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

hypernatraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	1 / 333 (0.30%)
occurrences (all)	0	0	1
hypertriglyceridaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	2 / 861 (0.23%)	0 / 333 (0.00%)
occurrences (all)	1	2	0
hyperuricaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
hypokalaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
hypomagnesaemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	1 / 453 (0.22%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	1	0	0
hyponatraemia			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
hypovitaminosis			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
impaired fasting glucose			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
insulin resistance			
alternative dictionary used: MedDRA 24.1			

subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
overweight			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	1 / 861 (0.12%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
underweight			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitamin b12 deficiency			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 24.1			
subjects affected / exposed	0 / 453 (0.00%)	0 / 861 (0.00%)	0 / 333 (0.00%)
occurrences (all)	0	0	0

Notes:

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 November 2018	- Modified schedule of activities, clinical laboratory tests, inclusion criteria and immunogenicity assessments sections; -Added ability for participants to receive psoriasis therapy with another agent(s) in post-treatment follow-up period; - Text clarified in blinding details; - Stricter discontinuation language for clinically significant systemic hypersensitivity events has been applied throughout the protocol; - Added expectation on timing of clinical assessments of tuberculosis (TB) risk.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

This study was terminated before completion of the long-term extension trial, due to strategic business decision made by the company.

Notes: