Clinical trial results:
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of Mirikizumab to Secukinumab and Placebo in Patients with Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2017-003286-10
Trial protocol	GB DE ES FR CZ HU PL IT
Global end of trial date	03 June 2020

Results information

Result version number	v1 (current)
This version publication date	19 March 2021
First version publication date	19 March 2021

Trial information

Trial identification

Sponsor protocol code	I6T-MC-AMAJ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03535194
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16504

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	03 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The reason for this study is to see how effective and safe mirikizumab is compared to secukinumab and placebo for 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	26 June 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: 87
Country: Number of subjects enrolled	Australia: 60
Country: Number of subjects enrolled	Canada: 86
Country: Number of subjects enrolled	Israel: 46
Country: Number of subjects enrolled	Japan: 145
Country: Number of subjects enrolled	Korea, Republic of: 55
Country: Number of subjects enrolled	Puerto Rico: 36
Country: Number of subjects enrolled	United States: 272
Country: Number of subjects enrolled	France: 66
Country: Number of subjects enrolled	Germany: 179
Country: Number of subjects enrolled	Hungary: 86
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Poland: 169
Country: Number of subjects enrolled	Spain: 73
Country: Number of subjects enrolled	Czechia: 95
Country: Number of subjects enrolled	United Kingdom: 6
Worldwide total number of subjects	1484
EEA total number of subjects	691

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)	1331
From 65 to 84 years	153
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

NA

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	250mg Q4W Mirikizumab

Arm description:

Participants received 250 Milligrams (mg) Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.

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

Dosage and administration details:

Participants received 250 Milligrams (mg) Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period.

Arm title	250mg Q4W Mirikizumab

Arm description:

Participants received 250mg Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.

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

Dosage and administration details:

Participants received 250mg Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period.

Arm title	Placebo

Arm description:

Participants received matching placebo at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during blinded induction period.

Arm type	Placebo

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

Dosage and administration details:

Participants received matching placebo at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during blinded induction period.

Arm title	300mg Secukinumab

Arm description:

Participants received 300mg Secukinumab at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during induction period.

Arm type	Active comparator
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 300mg Secukinumab at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during induction period.

Arm title	Japan GPP/EP

Arm description:

Participants received 250mg Mirikizumab Q4W by SC injection during induction period. A plaque psoriasis participant was misrandomized by the site.

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

Dosage and administration details:

Participants received 250mg Mirikizumab Q4W by SC injection during induction period.

Number of subjects in period 1	250mg Q4W Mirikizumab	250mg Q4W Mirikizumab	Placebo
Started	454	451	112
Received at least one dose of study drug	454	450	112
Completed	443	434	104
Not completed	11	17	8
Adverse event, serious fatal	-	1	-
Physician decision	1	1	-
Consent withdrawn by subject	3	4	3
Screen Failure	-	1	-
Adverse event, non-fatal	2	2	1
Lost to follow-up	3	5	2
Lack of efficacy	1	3	2

Protocol deviation	1	-	-

Number of subjects in period 1	300mg Secukinumab	Japan GPP/EP
Started	448	19
Received at least one dose of study drug	448	19
Completed	437	19
Not completed	11	0
Adverse event, serious fatal	-	-
Physician decision	-	-
Consent withdrawn by subject	2	-
Screen Failure	-	-
Adverse event, non-fatal	3	-
Lost to follow-up	3	-
Lack of efficacy	2	-
Protocol deviation	1	-

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	250mg Q8W Mirikizumab

Arm description:

Participants received 250mg Mirikizumab once every eight weeks (Q8W) in maintenance period. Participants received matching placebo to blind Secukinumab.

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

Dosage and administration details:

Participants received 250mg Mirikizumab once every eight weeks (Q8W) in maintenance period.

Arm title	125mg Q8W Mirikizumab

Arm description:

Participants received 125mg Mirikizumab once every eight weeks (Q8W) in maintenance period. Participants received matching placebo to blind Secukinumab.

Arm type	Experimental

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

Dosage and administration details:

Participants received 125mg Mirikizumab once every eight weeks (Q8W) in maintenance period.

Arm title	250mg Mirikizumab

Arm description:

Participants received 250mg Mirikizumab Q4W from week 16 to 32 followed by 250mg Mirikizumab Q8W from week 32 to 48 in maintenance period. Participants received matching placebo to blind Secukinumab.

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

Dosage and administration details:

Participants received 250mg Mirikizumab Q4W from week 16 to 32 followed by 250mg Mirikizumab Q8W from week 32 to 48 in maintenance period.

Arm title	300mg Secukinumab

Arm description:

Participants received 300mg Secukinumab Q4W from week 16 to 52 in maintenance period.

Arm type	Active comparator
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 300mg Secukinumab Q4W from week 16 to 52 in maintenance period.

Arm title	Japan GPP/EP

Arm description:

Participants received 250mg Q8W by SC injection in maintenance period.

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

Dosage and administration details:

Participants received 250mg Q8W by SC injection in maintenance period.

Number of subjects in period 2	250mg Q8W Mirikizumab	125mg Q8W Mirikizumab	250mg Mirikizumab
Started	443	434	104
Completed	421	418	96
Not completed	22	16	8
Physician decision	1	2	-
Consent withdrawn by subject	7	2	1
Adverse event, non-fatal	6	5	1
Unknown	1	2	-
Pregnancy	-	-	-
Lost to follow-up	4	2	1
Lack of efficacy	3	2	5
Protocol deviation	-	1	-

Number of subjects in period 2	300mg Secukinumab	Japan GPP/EP
Started	437	19
Completed	400	13
Not completed	37	6
Physician decision	2	-
Consent withdrawn by subject	8	-
Adverse event, non-fatal	11	4
Unknown	-	-
Pregnancy	2	-
Lost to follow-up	5	2
Lack of efficacy	9	-
Protocol deviation	-	-

Period 3	
Period 3 title	Post-Treatment Followup Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms	
Are arms mutually exclusive?	Yes

Arm title	250mg Q4W/250mg Q8W Mirikizumab
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	250mg Q4W/125mg Q8W Mirikizumab
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Placebo/250mg Mirikizumab
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	300mg Secukinumab
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Japan GPP/EP
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3[1]	250mg Q4W/250mg Q8W Mirikizumab	250mg Q4W/125mg Q8W Mirikizumab	Placebo/250mg Mirikizumab
Started	38	35	18
Completed	27	21	7
Not completed	11	14	11
Consent withdrawn by subject	2	2	3
Physician decision	-	2	1
Adverse event, non-fatal	4	5	1
Unknown	1	-	-
Lost to follow-up	1	1	1
Lack of efficacy	3	4	5

Number of subjects in period 3[1]	300mg Secukinumab	Japan GPP/EP
Started	47	8
Completed	23	8
Not completed	24	0
Consent withdrawn by subject	6	-
Physician decision	1	-
Adverse event, non-fatal	8	-
Unknown	5	-

Lost to follow-up	-	-
Lack of efficacy	4	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who discontinued/completed Induction/Maintenance had option to enter posttreatment.

Baseline characteristics

Reporting groups	
Reporting group title	250mg Q4W Mirikizumab
Reporting group description:	
Participants received 250 Milligrams (mg) Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	250mg Q4W Mirikizumab
Reporting group description:	
Participants received 250mg Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during blinded induction period.	
Reporting group title	300mg Secukinumab
Reporting group description:	
Participants received 300mg Secukinumab at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during induction period.	
Reporting group title	Japan GPP/EP
Reporting group description:	
Participants received 250mg Mirikizumab Q4W by SC injection during induction period. A plaque psoriasis participant was misrandomized by the site.	

Reporting group values	250mg Q4W Mirikizumab	250mg Q4W Mirikizumab	Placebo
Number of subjects	454	451	112
Age categorical Units: Subjects			
<65	417	398	103
>=65	37	53	9
Gender categorical Units: Subjects			
Female	158	140	30
Male	296	311	82
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	9	15	4
Not Hispanic or Latino	79	71	12
Unknown or Not Reported	366	365	96
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	2	1
Asian	81	66	12
Native Hawaiian or Other Pacific Islander	1	1	0
Black or African American	7	7	2
White	361	372	97
More than one race	2	2	0
Unknown or Not Reported	0	1	0

Reporting group values	300mg Secukinumab	Japan GPP/EP	Total
Number of subjects	448	19	1484
Age categorical Units: Subjects			
<65	399	14	1331
>=65	49	5	153
Gender categorical Units: Subjects			
Female	137	1	466
Male	311	18	1018
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	10	0	38
Not Hispanic or Latino	72	0	234
Unknown or Not Reported	366	19	1212
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	0	7
Asian	70	19	248
Native Hawaiian or Other Pacific Islander	1	0	3
Black or African American	8	0	24
White	365	0	1195
More than one race	2	0	6
Unknown or Not Reported	0	0	1

End points

End points reporting groups

Reporting group title	250mg Q4W Mirikizumab
Reporting group description:	
Participants received 250 Milligrams (mg) Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	250mg Q4W Mirikizumab
Reporting group description:	
Participants received 250mg Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during blinded induction period.	
Reporting group title	300mg Secukinumab
Reporting group description:	
Participants received 300mg Secukinumab at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during induction period.	
Reporting group title	Japan GPP/EP
Reporting group description:	
Participants received 250mg Mirikizumab Q4W by SC injection during induction period. A plaque psoriasis participant was misrandomized by the site.	
Reporting group title	250mg Q8W Mirikizumab
Reporting group description:	
Participants received 250mg Mirikizumab once every eight weeks (Q8W) in maintenance period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	125mg Q8W Mirikizumab
Reporting group description:	
Participants received 125mg Mirikizumab once every eight weeks (Q8W) in maintenance period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	250mg Mirikizumab
Reporting group description:	
Participants received 250mg Mirikizumab Q4W from week 16 to 32 followed by 250mg Mirikizumab Q8W from week 32 to 48 in maintenance period. Participants received matching placebo to blind Secukinumab.	
Reporting group title	300mg Secukinumab
Reporting group description:	
Participants received 300mg Secukinumab Q4W from week 16 to 52 in maintenance period.	
Reporting group title	Japan GPP/EP
Reporting group description:	
Participants received 250mg Q8W by SC injection in maintenance period.	
Reporting group title	250mg Q4W/250mg Q8W Mirikizumab
Reporting group description:	
.Participants did not receive any intervention in post-treatment follow-up period.	
Reporting group title	250mg Q4W/125mg Q8W Mirikizumab
Reporting group description: -	
Reporting group title	Placebo/250mg Mirikizumab
Reporting group description: -	
Reporting group title	300mg Secukinumab
Reporting group description: -	
Reporting group title	Japan GPP/EP

Reporting group description: -

Subject analysis set title	Mirikizumab 250mg Q4W/250mg Q8W
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received 250 Milligrams (mg) Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period followed by 250mg Mirikizumab once every eight weeks (Q8W) in maintenance period.

Subject analysis set title	250mg Mirikizumab /125mg Q8W
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received 250 Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period followed by 125mg Mirikizumab once every eight weeks (Q8W) in maintenance period.

Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received matching placebo at weeks 0, 1, 2, 3, 4, 8, and 12 by subcutaneous injection during blinded induction period.

Subject analysis set title	250mg Q4W Mirikizumab
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received 250 mg Mirikizumab once Q4W by subcutaneous injection during blinded induction period.

Primary: Percentage of Participants with a Static Physician's Global Assessment (sPGA) of (0,1) with at Least a 2-point Improvement from Baseline

End point title	Percentage of Participants with a Static Physician's Global Assessment (sPGA) of (0,1) with at Least a 2-point Improvement from Baseline[1]

End point description:

The sPGA is the physician's determination of the participant's psoriasis lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's psoriasis 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.

Analysis population description (APD): All randomized participants.

End point type	Primary

End point timeframe:

Week 16

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	76.3 (72.4 to 80.3)	6.3 (1.8 to 10.7)	79.7 (77.0 to 82.3)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v 250mg Q4W Mirikizumab
Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	73.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.2
upper limit	78.7

Primary: Percentage of Participants Achieving a ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) from Baseline

End point title	Percentage of Participants Achieving a ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) from Baseline[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, yielding an overall score of 0 for no psoriasis (PsO) to 72 for the most severe disease. 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.

End point type	Primary

End point timeframe:

Week 16

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	72.8 (68.6 to 76.9)	6.3 (1.8 to 10.7)	74.4 (71.5 to 77.2)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo
Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	68
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.7
upper limit	73.3

Secondary: Percentage of Participants Achieving a 75% Improvement in PASI 75

End point title	Percentage of Participants Achieving a 75% Improvement in PASI 75[3]

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, yielding an overall score of 0 for no psoriasis (PsO) to 72 for the most severe disease. 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.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	89.5 (86.7 to 92.3)	8.0 (3.0 to 13.1)	89.5 (87.5 to 91.5)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	81.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	76.1
upper limit	87

Secondary: Percentage of Participants with ≤1% of Body Surface Area (BSA) with Psoriasis Involvement

End point title	Percentage of Participants with ≤1% of Body Surface Area (BSA) with Psoriasis Involvement[4]

End point description:

The BSA is the percentage involvement of psoriasis on each participant's body surface on a continuous scale from 0% (no involvement) to 100% (full involvement), in which 1% corresponds to the size of the participant's hand (including the palm, fingers, and thumb). The total BSA affected was the summation of individual regions affected. Percentage response is calculated by number of participants with a response divided by number of participants with non-missing values multiplied by 100.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	54.5 (49.9 to 59.1)	1.8 (0.0 to 4.2)	53.1 (49.9 to 56.4)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	51.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.6
upper limit	55.8

Secondary: Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 in Those with PSS Symptom Score of ≥1 at Baseline

End point title	Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 in Those with PSS Symptom Score of ≥1 at Baseline[5]

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 a signs score of 0 (no signs) to 30 (worst imaginable signs) will be reported. Percentage response is calculated by number of participants with a response divided by number of participants with non-missing values multiplied by 100.

APD: All randomized participants with PSS symptom score of ≥1 at baseline.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	414	108	849	
Units: percentage of participants				
number (confidence interval 95%)	28.7 (24.4 to 33.1)	1.9 (0.0 to 4.4)	25.0 (22.1 to 27.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	957
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	23.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.3
upper limit	27.1

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[6]

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. Percentage response is calculated by number of participants with a response divided by number of participants with non-missing values multiplied by 100.

End point type	Secondary

End point timeframe:

Week 16

APD: All randomized participants with baseline DLQI Total Score ≥5.

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	396	101	821	
Units: percentage of participants				
number (confidence interval 95%)	60.4 (55.5 to 65.2)	5.9 (1.3 to 10.6)	59.6 (56.2 to 62.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo
Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	53.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.7
upper limit	59.3

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

End point title	Change from Baseline in Palmoplantar Psoriasis Severity Index (PPASI) Total Score in Participants with Palmoplantar Involvement at Baseline[7]

End point description:

The Palmoplantar PASI 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. Least Squares Mean (LS Mean) was calculated using mixed model repeated measures (MMRM) model with treatment, baseline value, visit, the interaction of the baseline value-by-visit, the interaction of treatment by-visit, and previous exposure to biologic therapy (yes/no), body weight (<100 kg or >=100 kg), and geographic region (North America or Other) as covariates.

APD: All randomized participants who had palmoplantar involvement at baseline.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	84	18	191	
Units: Score on a scale				
least squares mean (standard error)	-5.79 (± 0.541)	-1.33 (± 1.030)	-6.28 (± 0.383)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-4.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.01
upper limit	-2.88
Variability estimate	Standard error of the mean
Dispersion value	1.05

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[8]

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 16

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	387	90	789	
Units: Score on a scale				
least squares mean (standard error)	-18.22 (± 0.365)	-3.62 (± 0.676)	-18.78 (± 0.286)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	879
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-15.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.51
upper limit	-13.8
Variability estimate	Standard error of the mean
Dispersion value	0.692

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

End point title	Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Total Score in Participants with Fingernail Involvement at Baseline[9]

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 16

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	235	54	492	
Units: Score on a scale				
least squares mean (standard error)	-11.24 (± 0.774)	0.20 (± 1.494)	-9.38 (± 0.580)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	546
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-9.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.63
upper limit	-6.55
Variability estimate	Standard error of the mean
Dispersion value	1.55

Secondary: Change from Baseline on the 36-Item Short-Form Health Survey (SF-36) Physical Component Summary (PCS)

End point title	Change from Baseline on the 36-Item Short-Form Health Survey (SF-36) Physical Component Summary (PCS)[10]

End point description:

SF-36 consists of 36 questions measuring 8 health domains: physical functioning, bodily pain, role limitations due to physical problems, role limitations due to emotional problems, general health perceptions, mental health, social function, and vitality. The patient's responses are solicited using Likert scales that vary in length, with 3-6 response options per item. The SF-36 can be scored into the 8 health domains named above and two overall summary scores: physical component summary (PCS) and mental component summary (MCS) scores. The domain and summary scores range from 0 to 100; higher scores indicate better levels of function and/or better health.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: Score on a scale				
least squares mean (standard error)	4.38 (± 0.358)	0.57 (± 0.633)	4.03 (± 0.291)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LSMean Difference
Point estimate	3.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	4.72
Variability estimate	Standard error of the mean
Dispersion value	0.642

Secondary: Change from Baseline on the SF-36 Mental Component Summary (MCS)

End point title	Change from Baseline on the SF-36 Mental Component Summary (MCS)[11]

End point description:

SF-36 consists of 36 questions measuring 8 health domains: physical functioning, bodily pain, role limitations due to physical problems, role limitations due to emotional problems, general health perceptions, mental health, social function, and vitality. The patient's responses are solicited using Likert scales that vary in length, with 3-6 response options per item. The SF-36 can be scored into the 8 health domains named above and two overall summary scores: physical component summary (PCS) and mental component summary (MCS) scores. The domain and summary scores range from 0 to 100; higher scores indicate better levels of function and/or better health.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: Score on a scale				
least squares mean (standard error)	4.21 (± 0.398)	0.50 (± 0.701)	4.45 (± 0.321)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	1017
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LSMean Difference
Point estimate	3.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.56
upper limit	5.35
Variability estimate	Standard error of the mean
Dispersion value	0.711

Secondary: Percenatage of Participants achieving Patient’s Global Assessment (PatGA) of disease severity of (0,1) with at least a 2-point improvement from baseline in patients with a baseline PatGA ≥2

End point title	Percenatage of Participants achieving Patient’s Global Assessment (PatGA) of disease severity of (0,1) with at least a 2-point improvement from baseline in patients with a baseline PatGA ≥2[12]

End point description:

The PatGA is a single-item self-reported instrument asking the participant to rate the severity of their psoriasis "today" by circling a number on the numeric rating scale from 0 (Clear = no psoriasis) to 5 (Severe = the worst their psoriasis has ever been). Percentage response is calculated by number of participants with a response divided by number of participants with non-missing values multiplied by 100.

APD: All randomized participants with non missing baseline PatGA >=2 data.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	433	110	883	
Units: percentage of participants				
number (confidence interval 95%)	71.8 (67.6 to 76.1)	7.3 (2.4 to 12.1)	72.3 (69.3 to 75.2)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo

Number of subjects included in analysis	993
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	65
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.3
upper limit	70.8

Secondary: Change from baseline for the Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI-PSO) Scores

End point title	Change from baseline for the Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI-PSO) Scores[13]

End point description:

The WPAI-PSO consists of 6 questions to determine employment status, hours missed from work because of psoriasis, hours missed from work for other reasons, hours actually worked, the degree to which psoriasis affected work productivity while at work, and the degree to which psoriasis affected activities outside of work. Four scores are derived: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score that combines absenteeism and presenteeism and impairment in activities performed outside of work. Each WPAI score is expressed as impairment percentages (0-100) with higher numbers indicating greater impairment and less productivity, that is, worse outcomes.

APD: All randomized participants with baseline employment status of yes.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	320	84	617	
Units: Score on a scale				
least squares mean (standard error)				
Absenteeism	-2.48 (± 0.995)	-0.48 (± 1.753)	-2.20 (± 0.844)	
Presenteeism	-18.95 (± 1.204)	-3.36 (± 2.104)	-18.95 (± 1.020)	
Overall work impairment	-18.49 (± 1.401)	-2.77 (± 2.448)	-19.21 (± 1.187)	
Impairment in Activities Performed Outside of Work	-25.71 (± 1.061)	-5.86 (± 1.847)	-24.17 (± 0.885)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Quick Inventory of Depressive Symptomatology (QIDS-SR16) Total Score in Those with a Baseline QIDS-SR16 Total Score ≥11.

End point title	Change from Baseline in Quick Inventory of Depressive Symptomatology (QIDS-SR16) Total Score in Those with a Baseline QIDS-SR16 Total Score ≥11.[14]

End point description:

QIDS-SR16 is a participant-administered, 16-item instrument intended to assess the existence and severity of symptoms of depression. A participant is asked to consider each statement as it relates to the way they have felt for the past 7 days and rate each on a 4-point scale: 0 (best) to 3 (worst). The sum of the 16 items corresponding to 9 depression domains [sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance (initial, middle and late insomnia or hypersomnia), decrease/increase in appetite/weight, and psychomotor agitation/retardation] to give a single total scores range from 0 to 27, with higher scores indicating greater symptom severity. Whereas 0-5 indicates no symptoms.

APD: All participants who had a baseline QIDS-SR16 total score >=11.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	44	5	93	
Units: score on a scale				
least squares mean (standard error)	-5.10 (± 0.935)	-4.79 (± 2.266)	-5.28 (± 0.733)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	250mg Q4W Mirikizumab v Placebo
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.826
Method	ANCOVA
Parameter estimate	LSMean Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.96
upper limit	3.96

Variability estimate	Standard error of the mean
Dispersion value	2.255

Secondary: Pharmacokinetics: Minimum Observed Serum Concentration at Steady State (Ctrough,ss) of Mirikizumab

End point title	Pharmacokinetics: Minimum Observed Serum Concentration at Steady State (Ctrough,ss) of Mirikizumab

End point description:

Minimum observed serum Ctrough,ss of Mirikizumab.

Analysis population description: All randomized participants who received at least one dose of study drug and had evaluable PK samples.

End point type	Secondary

End point timeframe:

Week 16

End point values	250mg Q4W Mirikizumab			
Subject group type	Subject analysis set			
Number of subjects analysed	809			
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	2.40 (± 112)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Static Physician's Global Assessment (sPGA) of (0,1) with at Least a 2-point Improvement from Baseline (Non-inferiority)

End point title	Percentage of Participants with a Static Physician's Global Assessment (sPGA) of (0,1) with at Least a 2-point Improvement from Baseline (Non-inferiority)[15]

End point description:

The sPGA is the physician's determination of the participant's psoriasis lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's psoriasis 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.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	76.3 (72.4 to 80.3)	6.3 (1.8 to 10.7)	79.7 (77.0 to 82.3)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	300mg Secukinumab v 250mg Q4W Mirikizumab
Number of subjects included in analysis	1353
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	7.9

Secondary: Percentage of Participants Achieving a ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) from Baseline (Non-inferiority)

End point title	Percentage of Participants Achieving a ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) from Baseline (Non-inferiority)[16]

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, yielding an overall score of 0 for no psoriasis (PsO) to 72 for the most severe disease. 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.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not planned to be reported for all arms.

End point values	300mg Secukinumab	Placebo	250mg Q4W Mirikizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	448	112	905	
Units: percentage of participants				
number (confidence interval 95%)	72.8 (68.6 to 76.9)	6.3 (1.8 to 10.7)	74.4 (71.5 to 77.2)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	300mg Secukinumab v 250mg Q4W Mirikizumab
Number of subjects included in analysis	1353
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	6.6

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 64 weeks

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Placebo / Induction Period

Reporting group description:

Participants received matching placebo by subcutaneous injection in induction period.

Reporting group title	300mg Secukinumab / Induction Period

Reporting group description:

Participants received matching placebo by subcutaneous injection in induction period.

Reporting group title	250 Mirikizumab Q4W / Induction Period

Reporting group description:

Participants received 250mg Mirikizumab once every four weeks (Q4W) by subcutaneous injection during blinded induction period.

Reporting group title	250 Mirikizumab Q4W - Japan GPP/EP / Induction Period

Reporting group description:

Participants received 250mg Mirikizumab Q4W by subcutaneous injection in induction period.

Reporting group title	300 Secukinumab / Maintenance Period

Reporting group description:

Participants received 300mg Secukinumab Q4W by subcutaneous injection from week 16 to 52 in maintenance period.

Reporting group title	125 Mirikizumab Q8W / Maintenance Period

Reporting group description:

Participants received 125mg Mirikizumab once every eight weeks (Q8W) by subcutaneous injection in maintenance period.

Reporting group title	250 Mirikizumab Q8W / Maintenance Period

Reporting group description:

Participants received 250mg Mirikizumab once every eight weeks (Q8W) by subcutaneous injection in maintenance period.

Reporting group title	250mg Mirikizumab / Maintenance Period

Reporting group description:

Participants received 250mg Mirikizumab Q4W from week 16 to 32 followed by 250mg Mirikizumab Q8W from week 32 to 48 by subcutaneous injection in maintenance period.

Reporting group title	250 Mirikizumab Q8W - Japan GPP/EP / Maintenance Period

Reporting group description:

Participants received 250mg Mirikizumab Q4W from week 16 to 32 followed by 250mg Mirikizumab Q8W from week 32 to 48 by subcutaneous injection in maintenance period.

Reporting group title	Placebo / Follow-up Period

Reporting group description:

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

Reporting group title	300mg Secukinumab / Follow-up Period

Reporting group description:

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

Reporting group title	250 Mirikizumab Q4W / Follow-up Period

Reporting group description:

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

Reporting group title	250 Mirikizumab Q4W - Japan GPP/EP / Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	250 Mirikizumab Q4W/125 Mirikizumab Q8W / Follow-up Period
Reporting group description: -	
Reporting group title	Placebo/250 Mirikizumab / Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	250 Mirikizumab Q4W/250 Mirikizumab Q8W / Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	250 Miriki Q4W/250 Miri Q8W - Japan GPP/EP / Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	
Reporting group title	300 Secukinumab/300 Secukinumab / Follow-up Period
Reporting group description:	
Participants did not receive any intervention in post- treatment follow-up period.	

Serious adverse events	Placebo / Induction Period	300mg Secukinumab / Induction Period	250 Mirikizumab Q4W / Induction Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 112 (0.00%)	11 / 448 (2.46%)	15 / 904 (1.66%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
malignant melanoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
mammoplasty			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fibula fracture			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 laceration			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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
spinal compression fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 flutter			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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
Ear and labyrinth disorders			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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			
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (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
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	250 Mirikizumab Q4W - Japan GPP/EP / Induction Period	300 Secukinumab / Maintenance Period	125 Mirikizumab Q8W / Maintenance Period
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 19 (10.53%)	15 / 437 (3.43%)	13 / 434 (3.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
haemangioma of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mammoplasty			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
fibula fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary contusion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anal abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (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

pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	250 Mirikizumab Q8W / Maintenance Period	250mg Mirikizumab / Maintenance Period	250 Mirikizumab Q8W - Japan GPP/EP / Maintenance Period
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 443 (2.26%)	0 / 104 (0.00%)	3 / 18 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 skin			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
malignant melanoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
mammoplasty			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
fibula fracture			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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
skin laceration			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 flutter			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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

umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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			
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (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
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo / Follow-up Period	300mg Secukinumab / Follow-up Period	250 Mirikizumab Q4W / Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
malignant melanoma			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
mammoplasty			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
depression			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
fibula fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 flutter			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
anal abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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

pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	250 Mirikizumab Q4W - Japan GPP/EP / Follow-up Period	250 Mirikizumab Q4W/125 Mirikizumab Q8W / Follow-up Period	Placebo/250 Mirikizumab / Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	3 / 29 (10.34%)	0 / 14 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 skin			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (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
malignant melanoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
mammoplasty			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
fibula fracture			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 laceration			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 flutter			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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

umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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			
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (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
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	250 Mirikizumab Q4W/250 Mirikizumab Q8W / Follow-up Period	250 Miriki Q4W/250 Miri Q8W - Japan GPP/EP / Follow-up Period	300 Secukinumab/300 Secukinumab / Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
gallbladder cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
malignant melanoma			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 iv			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
gender reassignment therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
mammoplasty			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
tenotomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
anaphylactic shock			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
bipolar disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
depression			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
fibula fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
incisional hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 myocardial infarction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 flutter			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
congestive cardiomyopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
cerebral infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
monoplegia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
sacral radiculopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
incarcerated inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
pustular psoriasis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
symphysiolysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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			
anal abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
meningitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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

pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (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

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

Non-serious adverse events	Placebo / Induction Period	300mg Secukinumab / Induction Period	250 Mirikizumab Q4W / Induction Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 112 (60.71%)	257 / 448 (57.37%)	520 / 904 (57.52%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
b-cell lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	0	2	4
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 112 (3.57%)	9 / 448 (2.01%)	24 / 904 (2.65%)
occurrences (all)	4	9	25
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cataract operation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	2
dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0

foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
lens extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
limb operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	1	0	2
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	1	0	2
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	6 / 448 (1.34%)	15 / 904 (1.66%)
occurrences (all)	1	6	16
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	5 / 904 (0.55%)
occurrences (all)	0	1	5
injection site bruising			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
injection site erythema			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	13 / 904 (1.44%)
occurrences (all)	0	4	27
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	2	1	1
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 112 (3.57%)	1 / 448 (0.22%)	21 / 904 (2.32%)
occurrences (all)	28	6	109
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	5 / 904 (0.55%)
occurrences (all)	0	0	8
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	4 / 448 (0.89%)	26 / 904 (2.88%)
occurrences (all)	1	7	64
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	2 / 904 (0.22%)
occurrences (all)	0	2	2
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	1	1	3
pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	6 / 904 (0.66%)
occurrences (all)	0	1	6
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
stress at work			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	0	2	5
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 112 (3.57%)	7 / 448 (1.56%)	13 / 904 (1.44%)
occurrences (all)	4	7	13
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
hypoxia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	6 / 904 (0.66%)
occurrences (all)	0	2	6
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	11 / 448 (2.46%)	7 / 904 (0.77%)
occurrences (all)	2	12	7

paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	4 / 904 (0.44%)
occurrences (all)	0	2	4
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	1	1	4
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	1	0	4
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	2	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	1	1	1

irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	1	0	2
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	4 / 904 (0.44%)
occurrences (all)	0	0	6
social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
Product issues			

device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	1 / 904 (0.11%)
occurrences (all)	0	4	1
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	3	0
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
biopsy skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	12 / 904 (1.33%)
occurrences (all)	0	2	12
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
blood iron decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood potassium increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
blood thyroid stimulating hormone decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	1 / 904 (0.11%)
occurrences (all)	0	2	1
blood uric acid increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
body temperature increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
female sex hormone level abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
protein urine present			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	3
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	1	2	3
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	6 / 904 (0.66%)
occurrences (all)	0	0	6
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	6 / 904 (0.66%)
occurrences (all)	0	1	6
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	4 / 904 (0.44%)
occurrences (all)	0	2	4
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	7 / 904 (0.77%)
occurrences (all)	0	0	8
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	2	1	3
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
palpitations			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
dizziness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	0 / 448 (0.00%)	9 / 904 (1.00%)
occurrences (all)	2	0	10
dysaesthesia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 112 (3.57%)	24 / 448 (5.36%)	44 / 904 (4.87%)
occurrences (all)	4	27	63
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	2
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	1	0	3
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	5	3
nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	2	0	1
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
somnolence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
syncope			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
leukocytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
leukopenia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	2 / 904 (0.22%)
occurrences (all)	0	3	2
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	2 / 904 (0.22%)
occurrences (all)	0	3	2
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	2 / 448 (0.45%)	5 / 904 (0.55%)
occurrences (all)	2	2	5
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	2 / 448 (0.45%)	2 / 904 (0.22%)
occurrences (all)	1	2	2
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	4 / 904 (0.44%)
occurrences (all)	0	2	4
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	0	0	3
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	17 / 448 (3.79%)	17 / 904 (1.88%)
occurrences (all)	2	37	19
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	0	0	3

duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	6 / 904 (0.66%)
occurrences (all)	0	4	8
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	1	7	3
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	2 / 904 (0.22%)
occurrences (all)	0	2	2
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	1	1	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	10 / 904 (1.11%)
occurrences (all)	1	1	10
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	4 / 448 (0.89%)	8 / 904 (0.88%)
occurrences (all)	4	4	10
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	3 / 448 (0.67%)	4 / 904 (0.44%)
occurrences (all)	1	3	4
Skin and subcutaneous tissue disorders			
acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	6 / 904 (0.66%)
occurrences (all)	1	1	6
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	4
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	3	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	1 / 904 (0.11%)
occurrences (all)	0	3	1

dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	4 / 448 (0.89%)	5 / 904 (0.55%)
occurrences (all)	0	4	5
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	0	2	3
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	11 / 904 (1.22%)
occurrences (all)	0	3	14
eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	1 / 904 (0.11%)
occurrences (all)	0	2	1
eczema nummular			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	0	0	3
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	3 / 904 (0.33%)
occurrences (all)	0	0	3
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	4 / 448 (0.89%)	22 / 904 (2.43%)
occurrences (all)	4	4	22
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	1 / 904 (0.11%)
occurrences (all)	0	3	1
rash papular			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2

skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	8 / 904 (0.88%)
occurrences (all)	0	1	10
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
pollakiuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 112 (2.68%)	5 / 448 (1.12%)	20 / 904 (2.21%)
occurrences (all)	5	5	25
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 112 (4.46%)	3 / 448 (0.67%)	22 / 904 (2.43%)
occurrences (all)	5	4	22
bone pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	0	1	3
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	0	1	3
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	8 / 904 (0.88%)
occurrences (all)	0	4	8
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	1	1	1
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	10 / 904 (1.11%)
occurrences (all)	0	3	10
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	5 / 904 (0.55%)
occurrences (all)	0	1	5
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	2	0	2
osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	6 / 904 (0.66%)
occurrences (all)	0	2	6
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	2 / 448 (0.45%)	2 / 904 (0.22%)
occurrences (all)	2	2	2
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	3	1
synovial cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
abscess jaw			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	4 / 448 (0.89%)	14 / 904 (1.55%)
occurrences (all)	1	4	14
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0

cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	5 / 904 (0.55%)
occurrences (all)	0	0	5
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	3 / 904 (0.33%)
occurrences (all)	0	3	3
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	4 / 904 (0.44%)
occurrences (all)	0	0	4
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	0	1	3
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	1	1	0
folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	2 / 448 (0.45%)	3 / 904 (0.33%)
occurrences (all)	1	3	3

fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 112 (1.79%)	3 / 448 (0.67%)	11 / 904 (1.22%)
occurrences (all)	2	3	11
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	2 / 448 (0.45%)	5 / 904 (0.55%)
occurrences (all)	1	2	5
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
genital infection female			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	3 / 904 (0.33%)
occurrences (all)	0	1	3
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	1	1	1
impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1

infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	7 / 448 (1.56%)	10 / 904 (1.11%)
occurrences (all)	1	7	10
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	3
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
mastitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	1	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	18 / 112 (16.07%)	55 / 448 (12.28%)	144 / 904 (15.93%)
occurrences (all)	22	71	168
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	6 / 448 (1.34%)	5 / 904 (0.55%)
occurrences (all)	0	6	5
oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1

otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	1 / 904 (0.11%)
occurrences (all)	0	2	1
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	9 / 448 (2.01%)	7 / 904 (0.77%)
occurrences (all)	1	9	7
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	1	1	0
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	6 / 448 (1.34%)	16 / 904 (1.77%)
occurrences (all)	1	6	16
sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	4 / 448 (0.89%)	11 / 904 (1.22%)
occurrences (all)	0	5	11

sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
syphilis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	5 / 448 (1.12%)	7 / 904 (0.77%)
occurrences (all)	0	5	7
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	6 / 448 (1.34%)	6 / 904 (0.66%)
occurrences (all)	1	6	8
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	1	0	1
tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 112 (3.57%)	39 / 448 (8.71%)	53 / 904 (5.86%)
occurrences (all)	5	46	64
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	6 / 448 (1.34%)	1 / 904 (0.11%)
occurrences (all)	0	6	1
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	0 / 904 (0.00%)
occurrences (all)	0	3	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	9 / 904 (1.00%)
occurrences (all)	0	1	9
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	4 / 904 (0.44%)
occurrences (all)	0	3	4
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	2 / 448 (0.45%)	0 / 904 (0.00%)
occurrences (all)	0	2	0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	0 / 904 (0.00%)
occurrences (all)	0	1	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	2
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	3 / 448 (0.67%)	1 / 904 (0.11%)
occurrences (all)	0	3	1
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
food craving			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
gout			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	2 / 904 (0.22%)
occurrences (all)	0	0	3
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 112 (0.89%)	3 / 448 (0.67%)	3 / 904 (0.33%)
occurrences (all)	1	3	3
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	2 / 904 (0.22%)
occurrences (all)	0	1	2
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	4 / 904 (0.44%)
occurrences (all)	0	0	5
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0

iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	0 / 904 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	1 / 448 (0.22%)	1 / 904 (0.11%)
occurrences (all)	0	1	1
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 112 (0.00%)	0 / 448 (0.00%)	1 / 904 (0.11%)
occurrences (all)	0	0	1

Non-serious adverse events	250 Mirikizumab Q4W - Japan GPP/EP / Induction Period	300 Secukinumab / Maintenance Period	125 Mirikizumab Q8W / Maintenance Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 19 (73.68%)	292 / 437 (66.82%)	271 / 434 (62.44%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
b-cell lymphoma			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	9 / 437 (2.06%)	8 / 434 (1.84%)
occurrences (all)	0	9	8
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
cataract operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lens extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
limb operation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	2	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	4 / 434 (0.92%)
occurrences (all)	0	1	4
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
cyst			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	6 / 434 (1.38%)
occurrences (all)	0	5	6
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	5 / 434 (1.15%)
occurrences (all)	0	5	6
injection site bruising			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	4 / 434 (0.92%)
occurrences (all)	0	0	6
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	3 / 434 (0.69%)
occurrences (all)	0	0	4

injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	8 / 434 (1.84%)
occurrences (all)	0	11	38
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	4 / 434 (0.92%)
occurrences (all)	0	0	8
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	3 / 437 (0.69%)	14 / 434 (3.23%)
occurrences (all)	2	4	24
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	4 / 434 (0.92%)
occurrences (all)	0	4	4
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	3 / 434 (0.69%)
occurrences (all)	0	4	3
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
stress at work			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	1 / 434 (0.23%)
occurrences (all)	0	3	1
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	2
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	1 / 434 (0.23%)
occurrences (all)	0	3	1
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	12 / 437 (2.75%)	7 / 434 (1.61%)
occurrences (all)	0	14	9
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
dyspnoea			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	4 / 434 (0.92%)
occurrences (all)	0	6	4
paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	1	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	6 / 437 (1.37%)	2 / 434 (0.46%)
occurrences (all)	0	6	2
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	1 / 434 (0.23%)
occurrences (all)	0	4	1
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	1	0	1
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1

social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
hepatic function abnormal			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	2 / 434 (0.46%)
occurrences (all)	0	4	2
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
biopsy skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	7 / 434 (1.61%)
occurrences (all)	0	3	8
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
blood iron decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
blood potassium increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
blood pressure increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
blood thyroid stimulating hormone decreased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
blood triglycerides increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	0 / 434 (0.00%)
occurrences (all)	0	4	0
blood uric acid increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
body temperature increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
female sex hormone level abnormal alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
fibrin d dimer increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	3	2
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
protein urine present			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	3 / 434 (0.69%)
occurrences (all)	0	1	3
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	4 / 434 (0.92%)
occurrences (all)	0	3	4
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	4 / 434 (0.92%)
occurrences (all)	0	5	4
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
eye injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	5 / 434 (1.15%)
occurrences (all)	0	1	7
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	4 / 434 (0.92%)
occurrences (all)	0	0	4
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2

patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	3	1
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
palpitations			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	1	0	1
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 19 (5.26%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	1	1	1
dysaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	9 / 437 (2.06%)	16 / 434 (3.69%)
occurrences (all)	0	14	20
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	4	2

nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	2
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
somnolence			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
leukopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	1	1	0

vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	1	0	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	4 / 434 (0.92%)
occurrences (all)	0	9	4
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 19 (10.53%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	2	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	5 / 437 (1.14%)	6 / 434 (1.38%)
occurrences (all)	1	27	6
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0

dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	4 / 434 (0.92%)
occurrences (all)	0	0	4
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	3 / 434 (0.69%)
occurrences (all)	0	10	3
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	2	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	2 / 434 (0.46%)
occurrences (all)	0	6	4
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			

acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
acne			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	4	1
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	5 / 434 (1.15%)
occurrences (all)	0	5	5
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	1	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	10 / 437 (2.29%)	6 / 434 (1.38%)
occurrences (all)	1	11	6

eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eczema nummular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	3	1
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1

night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 19 (10.53%)	8 / 437 (1.83%)	2 / 434 (0.46%)
occurrences (all)	2	8	2
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
rash papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	3 / 434 (0.69%)
occurrences (all)	0	2	3
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	2
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	8 / 437 (1.83%)	18 / 434 (4.15%)
occurrences (all)	0	9	19
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	1	0	0
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	13 / 437 (2.97%)	19 / 434 (4.38%)
occurrences (all)	0	14	19
bone pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1

foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	3 / 434 (0.69%)
occurrences (all)	0	4	3
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	3 / 434 (0.69%)
occurrences (all)	0	0	4
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	5 / 434 (1.15%)
occurrences (all)	0	3	5

osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	5 / 434 (1.15%)
occurrences (all)	0	3	5
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	3 / 437 (0.69%)	2 / 434 (0.46%)
occurrences (all)	1	3	2
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
synovial cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	0 / 434 (0.00%)
occurrences (all)	0	4	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
abscess jaw			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
abscess limb			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	1	2	1
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	8 / 437 (1.83%)	9 / 434 (2.07%)
occurrences (all)	0	8	10
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	2 / 434 (0.46%)
occurrences (all)	0	3	2
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	8 / 437 (1.83%)	4 / 434 (0.92%)
occurrences (all)	0	9	4
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	3 / 434 (0.69%)
occurrences (all)	0	2	3
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
ear infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	0 / 434 (0.00%)
occurrences (all)	0	4	0
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	1	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	6 / 437 (1.37%)	4 / 434 (0.92%)
occurrences (all)	0	6	4
fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	1 / 434 (0.23%)
occurrences (all)	0	6	1
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	10 / 437 (2.29%)	9 / 434 (2.07%)
occurrences (all)	1	10	9
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	4 / 434 (0.92%)
occurrences (all)	0	3	4
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
genital infection female			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	3 / 434 (0.69%)
occurrences (all)	0	0	3
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	0	2	2
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0

impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	0 / 434 (0.00%)
occurrences (all)	0	5	0
infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	5 / 434 (1.15%)
occurrences (all)	0	3	5
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
mastitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 19 (21.05%)	61 / 437 (13.96%)	60 / 434 (13.82%)
occurrences (all)	5	81	73
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	1 / 434 (0.23%)
occurrences (all)	0	3	1
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	3 / 434 (0.69%)
occurrences (all)	0	4	5

oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	7 / 437 (1.60%)	2 / 434 (0.46%)
occurrences (all)	0	8	2
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	2 / 437 (0.46%)	2 / 434 (0.46%)
occurrences (all)	1	3	2
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	13 / 437 (2.97%)	6 / 434 (1.38%)
occurrences (all)	0	16	7
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	4 / 437 (0.92%)	2 / 434 (0.46%)
occurrences (all)	0	4	2
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	5 / 434 (1.15%)
occurrences (all)	0	2	6

sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	6 / 437 (1.37%)	7 / 434 (1.61%)
occurrences (all)	0	6	7
sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
syphilis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	3 / 437 (0.69%)	2 / 434 (0.46%)
occurrences (all)	1	3	4
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	3 / 434 (0.69%)
occurrences (all)	0	0	3
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	8 / 437 (1.83%)	2 / 434 (0.46%)
occurrences (all)	0	8	2
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	0 / 434 (0.00%)
occurrences (all)	0	3	0

tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 19 (5.26%)	35 / 437 (8.01%)	30 / 434 (6.91%)
occurrences (all)	2	46	40
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	5 / 437 (1.14%)	3 / 434 (0.69%)
occurrences (all)	0	5	3
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	3
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	0 / 434 (0.00%)
occurrences (all)	0	2	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	3 / 434 (0.69%)
occurrences (all)	0	1	3
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	2 / 434 (0.46%)
occurrences (all)	0	0	2
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
food craving			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
gout			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	1 / 434 (0.23%)
occurrences (all)	0	1	1
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	2 / 437 (0.46%)	1 / 434 (0.23%)
occurrences (all)	0	2	1
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	3 / 437 (0.69%)	0 / 434 (0.00%)
occurrences (all)	0	3	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1

increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	1 / 434 (0.23%)
occurrences (all)	0	0	1
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	0 / 434 (0.00%)
occurrences (all)	0	1	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	1 / 437 (0.23%)	2 / 434 (0.46%)
occurrences (all)	0	1	2
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 437 (0.00%)	0 / 434 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	250 Mirikizumab Q8W / Maintenance Period	250mg Mirikizumab / Maintenance Period	250 Mirikizumab Q8W - Japan GPP/EP / Maintenance Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	282 / 443 (63.66%)	0 / 104 (0.00%)	14 / 18 (77.78%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
b-cell lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	8 / 443 (1.81%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	8	0	0
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cataract operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lens extraction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
limb operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
chest pain			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	6 / 443 (1.35%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
injection site bruising			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	28	0	0
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	14 / 443 (3.16%)	0 / 104 (0.00%)	2 / 18 (11.11%)
occurrences (all)	35	0	5
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
stress at work			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	10	0	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	6	0	1
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dyspnoea			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hypoxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	11 / 443 (2.48%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	11	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	9	0	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
biopsy skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
blood iron decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
blood potassium increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blood pressure increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
blood thyroid stimulating hormone decreased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
blood triglycerides increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
blood uric acid increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
body temperature increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
female sex hormone level abnormal alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
protein urine present			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
palpitations			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
dysaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	19 / 443 (4.29%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	38	0	0
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0

nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
leukopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1

vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	9 / 443 (2.03%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	10	0	0
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	7 / 443 (1.58%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	8	0	0
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			

acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	9 / 443 (2.03%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	9	0	0
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0

eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
eczema nummular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
rash papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	13 / 443 (2.93%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	17	0	1
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	19 / 443 (4.29%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	22	0	1
bone pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	7 / 443 (1.58%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0

osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	8 / 443 (1.81%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	8	0	0
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
synovial cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
synovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
abscess jaw			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	9 / 443 (2.03%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	9	0	0
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	7 / 443 (1.58%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
genital infection female			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0

impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
mastitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	67 / 443 (15.12%)	0 / 104 (0.00%)	4 / 18 (22.22%)
occurrences (all)	82	0	4
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 443 (0.90%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0

sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	7 / 443 (1.58%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	7	0	1
sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
syphilis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	29 / 443 (6.55%)	0 / 104 (0.00%)	1 / 18 (5.56%)
occurrences (all)	36	0	1
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	5 / 443 (1.13%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 443 (0.68%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
food craving			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 443 (0.45%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 443 (0.23%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 443 (0.00%)	0 / 104 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo / Follow-up Period	300mg Secukinumab / Follow-up Period	250 Mirikizumab Q4W / Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
b-cell lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cataract operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lens extraction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
limb operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site bruising			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
stress at work			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyspnoea			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
biopsy skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood iron decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood potassium increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood pressure increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone decreased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
body temperature increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
female sex hormone level abnormal alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
protein urine present			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
palpitations			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eczema nummular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bone pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abscess jaw			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
genital infection female			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mastitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
syphilis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
food craving			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	250 Mirikizumab Q4W - Japan GPP/EP / Follow-up Period	250 Mirikizumab Q4W/125 Mirikizumab Q8W / Follow-up Period	Placebo/250 Mirikizumab / Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	3 / 29 (10.34%)	4 / 14 (28.57%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
b-cell lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cataract operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lens extraction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
limb operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site bruising			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
stress at work			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dyspnoea			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
biopsy skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood iron decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood potassium increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
body temperature increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
female sex hormone level abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
protein urine present			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
palpitations			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 1 (100.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eczema nummular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bone pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abscess jaw			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
genital infection female			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	1 / 29 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mastitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
syphilis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
food craving			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 29 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	250 Mirikizumab Q4W/250 Mirikizumab Q8W / Follow-up Period	250 Miriki Q4W/250 Miri Q8W - Japan GPP/EP / Follow-up Period	300 Secukinumab/300 Secukinumab / Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 35 (17.14%)	2 / 6 (33.33%)	7 / 43 (16.28%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
b-cell lymphoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lentigo maligna			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lung adenocarcinoma stage i			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neoplasm			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neoplasm skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oral fibroma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
prostate cancer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

uterine leiomyoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
arteriosclerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
peripheral venous disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
raynaud's phenomenon			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
thrombophlebitis superficial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
venous thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
white coat hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
antiviral prophylaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
bile duct stent insertion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
cataract operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cervix cryotherapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cholangiostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
cholecystectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dental care			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

dental prosthesis placement			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
endodontic procedure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
female sterilisation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
foot operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hernia repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
infusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
intestinal polypectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
joint surgery			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lens extraction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
limb operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lipoma excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mass excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
meniscus removal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nephrostomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
percutaneous coronary intervention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
phlebectomy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rehabilitation therapy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

removal of foreign body			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rotator cuff repair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin neoplasm excision			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
varicose vein operation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chest discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dehiscence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
granuloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site bruising			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

injection site oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
swelling face			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
food allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
multiple allergies			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rubber sensitivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
seasonal allergy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
selective igg subclass deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menopause			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
stress at work			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
balanoposthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
breast calcifications			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
breast mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ectropion of cervix			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oligospermia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
penile erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
testicular pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

vaginal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vulvovaginal dryness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
bronchial hyperreactivity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 35 (5.71%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	2	0	0
dysphonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dyspnoea			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
interstitial lung disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
laryngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nasal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nasal polyps			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nasal septum deviation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
paranasal sinus discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pharyngeal erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
productive cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
respiratory disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

respiratory distress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
throat tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

abnormal dreams			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
acute stress disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
alcoholic psychosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
attention deficit hyperactivity disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
burnout syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
loss of libido			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mood altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

social anxiety disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
device physical property issue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
biliary dilatation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatic fibrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatic function abnormal			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pneumobilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
anti-actin antibody positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
aspiration joint			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
biopsy skin			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	1 / 6 (16.67%)	0 / 43 (0.00%)
occurrences (all)	0	1	0
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood creatine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood iron decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood potassium increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood pressure increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood thyroid stimulating hormone decreased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
body temperature increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
female sex hormone level abnormal alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

gamma-glutamyltransferase abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haemoglobin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hepatitis e virus test positive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymph node palpable			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphocyte morphology abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mammogram			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
occult blood			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
panendoscopy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
platelet count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

prostatic specific antigen increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
protein urine present			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
red blood cell count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
transaminases increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	1 / 6 (16.67%)	0 / 43 (0.00%)
occurrences (all)	0	1	0
weight increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chemical burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye contusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
face injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
head injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

heat stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
injury corneal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ligament injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
limb crushing injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lower limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mallet finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
multiple injuries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

patella fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
post-traumatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
road traffic accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
scratch			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sternal injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
traumatic haematoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

traumatic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
upper limb fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
distichiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
coronary artery disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
palpitations			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ventricular extrasystoles			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
burning sensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cervicobrachial syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypertonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
loss of consciousness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

nerve compression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
notalgia paraesthetica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
presyncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
senile dementia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
taste disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
trigeminal neuralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
auditory disorder			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cerumen impaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypoacusis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

vertigo positional			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chalazion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
corneal disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erythema of eyelid			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye irritation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eyelid oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypermetropia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
meibomianitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
posterior capsule opacification			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

vision blurred			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
abdominal tenderness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
anal fissure			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chilaiditi's syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
diverticulum intestinal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	1 / 6 (16.67%)	0 / 43 (0.00%)
occurrences (all)	0	1	0

dry mouth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
duodenitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
enlarged uvula			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastric disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastric polyps			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal sphincter insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

gingival pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hiatus hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
inflammatory bowel disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
inguinal hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
intestinal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
loose tooth			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lumbar hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
odynophagia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oral pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
paraesthesia oral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

peptic ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
saliva altered			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tongue discolouration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
traumatic occlusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

acanthosis nigricans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
angioedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
asteatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dermatitis allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
drug eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ecchymosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

eczema asteatotic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eczema nummular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
granuloma annulare			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hand dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ingrown hair			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
keratosis pilaris			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lentigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
leukoplakia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lichen planus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lichen sclerosus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
macule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
myxoid cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nail psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

night sweats			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
onychoclasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
papulopustular rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
photosensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
photodermatosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pityriasis rosea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pityriasis rubra pilaris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
polymorphic light eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
post inflammatory pigmentation change			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
prurigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pruritus allergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

rash			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rash pruritic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rash vesicular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
seborrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sensitive skin			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin mass			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
solar dermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
toxic skin eruption			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
urticaria cholinergic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
urticaria chronic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

xeroderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
calculus urinary			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
haematuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
micturition urgency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
nocturia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
goitre			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
arthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
bone pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chondrocalcinosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
connective tissue disorder			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
exostosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
facet joint syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

foot deformity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
inclusion body myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
musculoskeletal discomfort			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
myositis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

osteitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
periarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
polyarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal hernia infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abscess jaw			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
asymptomatic bacteriuria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
bacterial vaginosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
bronchitis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

candida infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
demodicidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dermatophytosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
empyema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
enteritis infectious			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erythema infectiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
erythrasma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
eye infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

folliculitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
fungal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
furuncle			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
genital candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
genital herpes simplex			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
genital infection female			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
groin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

impetigo			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
kidney infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
labyrinthitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
localised infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
lyme disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mastitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mastoiditis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
mycoplasma infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
myringitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	2 / 6 (33.33%)	2 / 43 (4.65%)
occurrences (all)	0	2	2
onychomycosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oral candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0

oral fungal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
otitis externa			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
otitis media acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	1 / 6 (16.67%)	0 / 43 (0.00%)
occurrences (all)	0	1	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pharyngitis bacterial			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
sinusitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin bacterial infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin candida			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
staphylococcal abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
syphilis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tinea infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tinea cruris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tonsillitis bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

tooth infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 35 (2.86%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
viral pharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
viral sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
wound infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
food craving			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypocholesterolaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

increased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
metabolic syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
polydipsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 35 (0.00%)	0 / 6 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 February 2019	Revised major secondary endpoint so that DLQI (0,1) response will include a 5-point reduction and be assessed in patients with baseline DLQI 5 (also included this endpoint at other times as Other Secondary endpoints). Changed PPASI, PSSI, and NAPSI endpoints from "percent change" to "change."
30 September 2019	Added endpoint of proportion of patients achieving PASI 100 at Week 52 for superiority objective.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported