Clinical trial results:
A Multicenter Study with a Randomized, Double-Blind, Placebo-Controlled Induction Dosing Period Followed by a Randomized Withdrawal Maintenance Dosing Period to Evaluate the Efficacy and Safety of Mirikizumab in Patients with Moderate-to-Severe Plaque Psoriasis OASIS-1

Summary

EudraCT number	2017-003298-32
Trial protocol	DE PL
Global end of trial date	16 January 2020

Results information

Result version number	v1 (current)
This version publication date	16 September 2020
First version publication date	16 September 2020

Trial information

Trial identification

Sponsor protocol code	I6T-MC-AMAK

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03482011
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16505

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	16 January 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 April 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Korea, Republic of: 56
Country: Number of subjects enrolled	Puerto Rico: 20
Country: Number of subjects enrolled	United States: 85
Country: Number of subjects enrolled	Japan: 54
Country: Number of subjects enrolled	Taiwan: 61
Country: Number of subjects enrolled	Poland: 55
Country: Number of subjects enrolled	Mexico: 76
Country: Number of subjects enrolled	Germany: 74
Country: Number of subjects enrolled	Russian Federation: 49
Worldwide total number of subjects	530
EEA total number of subjects	129

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	482
From 65 to 84 years	48
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

No Text Available

Period 1

Period 1 title	Induction Period (16 Weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Q4W

Arm description:

Induction Period: Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Arm title	250 mg Miri Q4W

Arm description:

Induction Period: Participants received 250 milligrams (mg) mirikizumab (miri) administered SC Q4W.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Number of subjects in period 1	Placebo Q4W	250 mg Miri Q4W
Started	107	423
Received at least one dose of study drug	107	422
Completed	101	412
Not completed	6	11

Consent withdrawn by subject	2	5
Screen Failure	-	1
Adverse event, non-fatal	1	3
Lost to follow-up	-	1
Lack of efficacy	3	1

Period 2

Period 2 title	Maintenance Period (36 Weeks)
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	Placebo Q4W to Placebo Q8W (Placebo Responder)

Arm description:

Maintenance Period: Participants received placebo administered SC every 8 weeks (Q8W). Responders had ≥PASI 90.

Participants had received placebo administered SC Q4W during induction period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Arm title	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)

Arm description:

Maintenance Period: Participants received 250 mg mirikizumab administered SC Q4W during week 16 to week 32 and Q8W during week 40 and 48. Non-responders had < PASI 90.

Participants had received placebo administered SC Q4W during induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered SC.

Arm title	250 mg Miri Q4W Responders to Placebo Q8W

Arm description:
Maintenance Period: Participants received placebo administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered SC

Arm title	250 mg Miri Q4W Responders to 125 mg Miri Q8W

Arm description:
Maintenance Period: Participants received 125 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered SC.

Arm title	250 mg Miri Q4W Responder to 250 mg Miri Q8W

Arm description:
Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered SC.

Arm title	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders)

Arm description:

Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Non-responders had < PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Number of subjects in period 2	Placebo Q4W to Placebo Q8W (Placebo Responder)	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)	250 mg Miri Q4W Responders to Placebo Q8W
Started	7	94	91
Relapse	1 [1]	0 [2]	41 [3]
Roll Over to I6T-MC-AMAH(2017-003299-30)	6	88 [4]	86
Completed	6	90	86
Not completed	1	4	5
Physician decision	-	1	-
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	2
Lack of efficacy	1	2	1

Number of subjects in period 2	250 mg Miri Q4W Responders to 125 mg Miri Q8W	250 mg Miri Q4W Responder to 250 mg Miri Q8W	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders)
Started	90	91	140
Relapse	3 [5]	2 [6]	0 [7]
Roll Over to I6T-MC-AMAH(2017-003299-30)	85 [8]	87	121 [9]
Completed	86	87	123
Not completed	4	4	17
Physician decision	1	1	1
Consent withdrawn by subject	1	2	2
Adverse event, non-fatal	1	1	4
Lost to follow-up	-	-	1
Lack of efficacy	1	-	9

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants that completed Week 52 had the opportunity to roll over into study I6T-MC-AMAH (2017-003299-30).

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This represents the participants who relapsed.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants that completed Week 52 had the opportunity to roll over into study I6T-MC-AMAH (2017-003299-30).

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: All participants that completed Week 52 had the opportunity to roll over into study I6T-MC-AMAH (2017-003299-30).

Period 3

Period 3 title	Follow-up Period (12 Weeks)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Q4W to Placebo Q8W (Placebo Responder) - Follow-up(FU)

Arm description:

Follow-up Period: Participants did not receive drug during the follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo Q4W to 250mg Miri Q4W/Q8W (Placebo Non-Responder) - FU

Arm description:

Follow-up Period: Participants did not receive drug during the follow-up period.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	250 mg Miri Q4W Responders to Placebo Q8W - Follow-up
Arm description: Follow-up Period: Participants did not receive drug during the follow-up period.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	250 mg Miri Q4W Responders to 125 mg Miri Q8W - Follow-up
Arm description: Follow-up Period: Participants did not receive drug during the follow-up period.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	250 mg Miri Q4W Responder to 250 mg Miri Q8W - Follow-up
Arm description: Follow-up Period: Participants did not receive drug during the follow-up period.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders) - FU
Arm description: Follow-up Period: Participants did not receive drug during the follow-up period.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3[10]	Placebo Q4W to Placebo Q8W (Placebo Responder) - Follow-up(FU)	Placebo Q4W to 250mg Miri Q4W/Q8W (Placebo Non-Responder) - FU	250 mg Miri Q4W Responders to Placebo Q8W - Follow-up
Started	1	10	2
Completed	0	5	2
Not completed	1	5	0
Consent withdrawn by subject	-	2	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Lack of efficacy	1	3	-

Number of subjects in period 3[10]	250 mg Miri Q4W Responders to 125 mg Miri Q8W - Follow-up	250 mg Miri Q4W Responder to 250 mg Miri Q8W - Follow-up	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders) - FU
Started	4	4	21
Completed	3	2	4
Not completed	1	2	17
Consent withdrawn by subject	1	1	5
Physician decision	-	-	1

Adverse event, non-fatal	-	1	4
Lost to follow-up	-	-	1
Lack of efficacy	-	-	6

Notes:

[10] - 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: Not all participants that completed maintenance period continued to follow-up period.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo Q4W
Reporting group description:	
Induction Period: Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).	
Reporting group title	250 mg Miri Q4W
Reporting group description:	
Induction Period: Participants received 250 milligrams (mg) mirikizumab (miri) administered SC Q4W.	

Reporting group values	Placebo Q4W	250 mg Miri Q4W	Total
Number of subjects	107	423	530
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	45.7	46.4	
standard deviation	± 13.70	± 13.56	-
Gender categorical Units: Subjects			
Female	33	124	157
Male	74	299	373
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	13	17
Not Hispanic or Latino	11	53	64
Unknown or Not Reported	92	357	449
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	14	50	64
Asian	33	139	172
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	4	2	6
White	56	231	287
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
South Korea	11	45	56
Puerto Rico	5	15	20
United States	16	69	85
Japan	10	44	54
Taiwan	12	49	61
Poland	11	44	55
Mexico	15	61	76
Germany	16	58	74
Russia	11	38	49

End points

End points reporting groups

Reporting group title	Placebo Q4W
Reporting group description:	
Induction Period: Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).	

Reporting group title	250 mg Miri Q4W
Reporting group description:	
Induction Period: Participants received 250 milligrams (mg) mirikizumab (miri) administered SC Q4W.	

Reporting group title	Placebo Q4W to Placebo Q8W (Placebo Responder)
Reporting group description:	
Maintenance Period: Participants received placebo administered SC every 8 weeks (Q8W). Responders had ≥PASI 90. Participants had received placebo administered SC Q4W during induction period.	

Reporting group title	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)
Reporting group description:	
Maintenance Period: Participants received 250 mg mirikizumab administered SC Q4W during week 16 to week 32 and Q8W during week 40 and 48. Non-responders had < PASI 90. Participants had received placebo administered SC Q4W during induction period.	

Reporting group title	250 mg Miri Q4W Responders to Placebo Q8W
Reporting group description:	
Maintenance Period: Participants received placebo administered SC Q8W. Responders had ≥PASI 90. Participants had received 250 mirikizumab administered SC Q4W during induction period.	

Reporting group title	250 mg Miri Q4W Responders to 125 mg Miri Q8W
Reporting group description:	
Maintenance Period: Participants received 125 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90. Participants had received 250 mirikizumab administered SC Q4W during induction period.	

Reporting group title	250 mg Miri Q4W Responder to 250 mg Miri Q8W
Reporting group description:	
Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90. Participants had received 250 mirikizumab administered SC Q4W during induction period.	

Reporting group title	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders)
Reporting group description:	
Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Non-responders had < PASI 90. Participants had received 250 mirikizumab administered SC Q4W during induction period.	

Reporting group title	Placebo Q4W to Placebo Q8W (Placebo Responder) - Follow-up(FU)
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	Placebo Q4W to 250mg Miri Q4W/Q8W (Placebo Non-Responder) - FU
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250 mg Miri Q4W Responders to Placebo Q8W - Follow-up
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250 mg Miri Q4W Responders to 125 mg Miri Q8W - Follow-up
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250 mg Miri Q4W Responder to 250 mg Miri Q8W - Follow-up
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250 mg Miri Q4W to 250 mg Miri Q8W (Miri Non-Responders) - FU
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	

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

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

End point description:

The sPGA is the physician's determination of the participant's psoriasis (PsO) lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's PsO was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline.

Analysis Population Description (APD): All randomized participants.

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	6.5 (1.9 to 11.2)	69.3 (64.9 to 73.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis for sPGA (0,1)
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	63
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.5
upper limit	69.4

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

End point title	Percentage of Participants Achieving a ≥90% Improvement from Baseline in Psoriasis Area and Severity Score (PASI 90)

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).

Analysis Population Description: All randomized participants.

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	6.5 (1.9 to 11.2)	64.3 (59.7 to 68.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PASI 90
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	57.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.3
upper limit	64.4

Secondary: Percentage of Participants Achieving a ≥75% Improvement from Baseline in PASI (PASI 75)

End point title	Percentage of Participants Achieving a ≥75% Improvement from Baseline in PASI (PASI 75)

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).

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	0.9 (0.0 to 2.8)	17.0 (13.4 to 20.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PASI 75
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	15.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.6
upper limit	19.7

Secondary: Percentage of Participants Achieving a ≥75% Improvement from Baseline in PASI (PASI 75)

End point title	Percentage of Participants Achieving a ≥75% Improvement from Baseline in PASI (PASI 75)

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).

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	9.3 (3.8 to 14.9)	82.5 (78.9 to 86.1)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PASI 75
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	73.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.1
upper limit	80.1

Secondary: Percentage of Participants Achieving a ≥100% Improvement from Baseline in Psoriasis Area and Severity Score (PASI 100)

End point title	Percentage of Participants Achieving a ≥100% Improvement from Baseline in Psoriasis Area and Severity Score (PASI 100)

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, 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).

Analysis Population Description: All randomized participants.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	0.9 (0.0 to 2.8)	32.4 (27.9 to 36.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PASI 100
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	30.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	26
upper limit	35.7

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

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.

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	423		
Units: Percentage of participants				
number (confidence interval 95%)	0.9 (0.0 to 2.8)	49.2 (44.4 to 53.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis for BSA
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	48.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.9
upper limit	53.2

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

End point title	Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptoms Score of 0 in those with a PSS Symptoms Score ≥1 at Baseline

End point description:

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

Analysis Population Description: All randomized participants who had PSS symptoms score ≥1 at baseline.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	410		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 0.0)	19.0 (15.2 to 22.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PSS
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.5
upper limit	22.1

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

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

Analysis Population Description: All randomized participants who had a baseline DLQI Total Score ≥5.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	384		
Units: Percentage of participants				
number (confidence interval 95%)	5.4 (0.8 to 10.1)	54.7 (49.7 to 59.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis for DLQI
Comparison groups	Placebo Q4W v 250 mg Miri Q4W

Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	49.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.8
upper limit	56.4

Secondary: Percentage of Participants Maintaining Clinical Response (PASI 90) after Re-randomization at the Start of the Randomized Withdrawal Period

End point title	Percentage of Participants Maintaining Clinical Response (PASI 90) after Re-randomization at the Start of the Randomized Withdrawal Period

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).

Analysis Population Description: All re-randomized participants who were responders (≥PASI 90).

End point type	Secondary
End point timeframe:	
Week 52	

End point values	250 mg Miri Q4W Responders to Placebo Q8W	250 mg Miri Q4W Responders to 125 mg Miri Q8W	250 mg Miri Q4W Responder to 250 mg Miri Q8W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	90	91	
Units: Percentage of participants				
number (confidence interval 95%)	18.7 (10.7 to 26.7)	85.6 (78.3 to 92.8)	84.6 (77.2 to 92.0)	

Statistical analyses

Statistical analysis title	Statistical Analysis for PASI 90
Comparison groups	250 mg Miri Q4W Responders to Placebo Q8W v 250 mg Miri

	Q4W Responders to 125 mg Miri Q8W
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	66.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	56
upper limit	77.5

Statistical analysis title	Statistical Analysis for PASI 90
Comparison groups	250 mg Miri Q4W Responders to Placebo Q8W v 250 mg Miri Q4W Responder to 250 mg Miri Q8W
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	65.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.9
upper limit	77

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

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

End point description:

The 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.

Analysis population Description: All randomized participants who had palmoplantar involvement at baseline.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	111		
Units: score on a scale				
least squares mean (standard error)	-1.13 (± 1.29)	-5.83 (± 0.72)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PPASI Total Score
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	135
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-4.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.31
upper limit	-2.1
Variability estimate	Standard error of the mean
Dispersion value	1.32

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

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

End point description:

The PSSI is a physician assessment of erythema, induration and desquamation and percent of scalp that is covered with a scores range from 0 (none) to 4 (very severe). The composite score is derived from the sum of scores for erythema, induration, and desquamation multiplied by the score recorded for the extent of the scalp area involved, 1 (<10%) to 6 (90%-100%) with a total score ranging from 0 (less severity) to 72 (more severity). LS Mean was calculated using 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.

Analysis Population Description: All randomized participants who had scalp involvement at baseline.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	381		
Units: score on a scale				
least squares mean (standard error)	-2.70 (± 0.95)	-20.03 (± 0.55)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PSSI Total Score
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	475
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-17.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.28
upper limit	-15.39
Variability estimate	Standard error of the mean
Dispersion value	0.99

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	248		
Units: score on a scale				
least squares mean (standard error)	-2.04 (± 1.60)	-9.01 (± 0.89)		

Statistical analyses

Statistical analysis title	Statistical Analysis for NAPSI Total Score
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-6.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.37
upper limit	-3.58
Variability estimate	Standard error of the mean
Dispersion value	1.73

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

End point title	Change from Baseline on the Short Form (SF)-36 Physical Component Summary (PCS)

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. LS Mean was calculated using Analysis of covariance (ANCOVA) model with treatment and baseline value, previous exposure to biologic therapy (yes/no), body weight (<100 kg or >=100 kg), and geographic region (North America or Other) as fixed factors.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants who had a baseline and at least one post-baseline PCS value.

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106	418		
Units: score on a scale				
least squares mean (standard error)	0.35 (± 0.69)	5.21 (± 0.43)		

Statistical analyses

Statistical analysis title	Statistical Analysis for SF-36: PCS
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	4.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	6.22
Variability estimate	Standard error of the mean
Dispersion value	0.69

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)

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. LS Mean was calculated using Analysis of covariance (ANCOVA) model with treatment and baseline value, previous exposure to biologic therapy (yes/no), body weight (<100 kg or >=100 kg), and geographic region (North America or Other) as fixed factors.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants who had a baseline and at least one post-baseline MCS value.

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106	418		
Units: score on a scale				
least squares mean (standard error)	0.32 (± 0.73)	5.10 (± 0.46)		

Statistical analyses

Statistical analysis title	Statistical Analysis for SF-36: MCS
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	4.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.33
upper limit	6.23
Variability estimate	Standard error of the mean
Dispersion value	0.74

Secondary: Percentage of Participants with Patient's Global Assessment of Psoriasis (PatGA (0,1)) and >=2 Improvement From Baseline

End point title	Percentage of Participants with Patient's Global Assessment of Psoriasis (PatGA (0,1)) and >=2 Improvement From Baseline

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.

Analysis Population Description: All randomized participants who had a baseline >= 2.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	419		
Units: Percentage of participants				
number (confidence interval 95%)	1.0 (0.0 to 2.8)	69.5 (65.0 to 73.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis for PatGA(0,1)
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	523
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	68.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.2
upper limit	72.9

Secondary: Change from Baseline on the Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI-PSO)

End point title	Change from Baseline on the Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI-PSO)

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. LS Mean was calculated using Analysis of covariance (ANCOVA) model with treatment and baseline value, previous exposure to biologic therapy (yes/no), body weight (<100 kg or >=100 kg), and geographic region (North America or Other) as fixed factors.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Analysis Population Description: All randomized participants who had a baseline and at least one post-baseline WPAI-PSO value.

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106	418		
Units: score on a scale				
least squares mean (standard error)				
Absenteeism	0.10 (± 1.87)	-3.57 (± 1.12)		
Presenteeism	-4.54 (± 2.39)	-24.79 (± 1.42)		
Overall Absenteeism and Presenteeism	-3.45 (± 2.82)	-24.54 (± 1.68)		
Impairment in Activities Performed Outside of Work	-6.83 (± 2.27)	-29.73 (± 1.41)		

Statistical analyses

Statistical analysis title	Statistical Analysis for WPAI-PSO: Absenteeism
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	-0.06
Variability estimate	Standard error of the mean
Dispersion value	1.84

Statistical analysis title	Statistical Analysis for WPAI-PSO: Presenteeism
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-20.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.89
upper limit	-15.6

Variability estimate	Standard error of the mean
Dispersion value	2.37

Statistical analysis title	Overall Absenteeism and Presenteeism
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-21.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.56
upper limit	-15.62
Variability estimate	Standard error of the mean
Dispersion value	2.78

Statistical analysis title	Impairment in Activities Performed Outside of Work
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-22.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.39
upper limit	-18.43
Variability estimate	Standard error of the mean
Dispersion value	2.28

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

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. LS Mean was calculated using ANCOVA model with treatment and baseline value, previous exposure to biologic therapy (yes/no), body weight (<100 kg or >=100 kg), and geographic region (North America or Other) as fixed factors.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Analysis Population Description: All participants who received at least one dose of study drug who had a baseline QIDS-SR16 total score >=11.

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	35		
Units: score on a scale				
least squares mean (standard error)	-4.95 (± 1.94)	-4.42 (± 1.43)		

Statistical analyses

Statistical analysis title	Statistical Analysis for QIDS-SR16 Total Score
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.08
upper limit	4.14
Variability estimate	Standard error of the mean
Dispersion value	1.79

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

End point title	Induction Period: Pharmacokinetics (PK): Minimum Observed Serum Concentration at Steady State (Ctrough,ss) of Mirikizumab[1]

End point description:

Minimum observed serum concentration at steady state (Ctrough,ss) of mirikizumab.

Analysis Population Description: All participants who received at least one dose of study drug who had evaluable PK data.

End point type	Secondary

End point timeframe:

Week 16 Day 113

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: Only induction data were planned to be reported due to nature of the design of randomized withdrawal in the maintenance period.

End point values	250 mg Miri Q4W			
Subject group type	Reporting group			
Number of subjects analysed	387			
Units: micrograms per milliliter(micrograms/mL)				
geometric mean (geometric coefficient of variation)	2.00 (± 139)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) (0,1)

End point title	Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) (0,1)

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

Induction Period: All randomized participants who had a baseline and at least one post-baseline DLQI value.

End point values	Placebo Q4W	250 mg Miri Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	413		
Units: Percentage of participants				
number (confidence interval 95%)	8.7 (3.3 to 14.1)	57.1 (52.4 to 61.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis For DLQI (0,1)
Comparison groups	Placebo Q4W v 250 mg Miri Q4W
Number of subjects included in analysis	517
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	48.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.6
upper limit	55.9

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 64 Weeks

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Placebo Q4W

Reporting group description:

Induction Period: Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).

Reporting group title	250 mg Miri Q4W

Reporting group description:

Induction Period: Participants received 250 mg mirikizumab (miri) administered SC Q4W.

Reporting group title	250 mg Miri Q4W Responders to Placebo Q8W

Reporting group description:

Maintenance Period: Participants received placebo administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Reporting group title	250 mg Miri Q4W Responders to 125 mg Miri Q8W

Reporting group description:

Maintenance Period: Participants received 125 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Reporting group title	250 mg Miri Q4W Responder to 250 mg Miri Q8W

Reporting group description:

Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Responders had ≥PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Reporting group title	250mg Miri Q4W to 250mg Miri Q8W(Miri Non-Responders)

Reporting group description:

Maintenance Period: Participants received 250 mg mirikizumab administered SC Q8W. Non-responders had < PASI 90.

Participants had received 250 mirikizumab administered SC Q4W during induction period.

Reporting group title	Placebo Q4W to Placebo Q8W (Placebo Responder)

Reporting group description:

Maintenance Period: Participants received placebo administered SC Q8W. Responders had ≥PASI 90.

Participants had received placebo administered SC Q4W during induction period.

Reporting group title	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)

Reporting group description:

Maintenance Period: Participants received 250 mg mirikizumab administered SC Q4W during week 16 to week to week 32 and Q8W during week 40 and 48. Non-responders had < PASI 90.

Participants had received placebo administered SC Q4W during induction period.

Reporting group title	Relapse

Reporting group description:

Participants that relapsed were in the following arms:

Placebo Q4W to Placebo Q8W (Placebo Responder).

250 mg Miri Q4W Responders to Placebo Q8W.

250 mg Miri Q4W Responders to 125 mg Miri Q8W.

250 mg Miri Q4W Responder to 250 mg Miri Q8W.

Reporting group title	Placebo Q4W Discontinued During Induction-Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period. Participants discontinued (DC) before induction week 16 and counted as placebo non-responders.	
Reporting group title	250 Miri Q4W Discontinued During Induction-Follow-up
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period. Participants discontinued (DC) before induction week 16 and counted as miri non-responders	
Reporting group title	250 mg Miri Q4W to Placebo Q8W (Responders) Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250mg Miri Q4W to 125 mg Miri Q8W(Responders) Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250mg Miri Q4W to 250mg Miri Q8W(Responders) Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	250 miri Q4W to Miri nonresponder-Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	Placebo Q4W to Placebo Q8W (Placebo Responder) - Follow-up
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	
Reporting group title	Placebo Q4W to Placebo Non-Responder-Follow-up Period
Reporting group description:	
Follow-up Period: Participants did not receive drug during the follow-up period.	

Serious adverse events	Placebo Q4W	250 mg Miri Q4W	250 mg Miri Q4W Responders to Placebo Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 107 (1.87%)	5 / 422 (1.18%)	3 / 91 (3.30%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (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
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
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 fibrillation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
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			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (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
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
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			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (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 mg Miri Q4W Responders to 125 mg Miri Q8W	250 mg Miri Q4W Responder to 250 mg Miri Q8W	250mg Miri Q4W to 250mg Miri Q8W(Miri Non-Responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 90 (1.11%)	3 / 91 (3.30%)	0 / 140 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (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
Surgical and medical procedures			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (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
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
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 Q4W to Placebo Q8W (Placebo Responder)	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)	Relapse
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
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 Q4W Discontinued During Induction-Follow-up Period	250 Miri Q4W Discontinued During Induction-Follow-up	250 mg Miri Q4W to Placebo Q8W (Responders) Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
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	250mg Miri Q4W to 125 mg Miri Q8W(Responders) Follow-up Period	250mg Miri Q4W to 250mg Miri Q8W(Responders) Follow-up Period	250 miri Q4W to Miri nonresponder-Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
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 Q4W to Placebo Q8W (Placebo Responder) - Follow-up	Placebo Q4W to Placebo Non-Responder-Follow-up Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ligament rupture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
skull fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
tonsillectomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
epilepsy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
bile duct stone			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
glomerulonephritis membranous			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo Q4W	250 mg Miri Q4W	250 mg Miri Q4W Responders to Placebo Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 107 (47.66%)	199 / 422 (47.16%)	49 / 91 (53.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

anogenital warts			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
fibroma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	4
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
haematoma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	9 / 422 (2.13%)	3 / 91 (3.30%)
occurrences (all)	0	10	6
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
fat necrosis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	1	3	0
hyperthermia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
influenza like illness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
injection site erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
injection site induration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 107 (4.67%)	22 / 422 (5.21%)	2 / 91 (2.20%)
occurrences (all)	20	109	48
injection site pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	5 / 422 (1.18%)	0 / 91 (0.00%)
occurrences (all)	0	11	0

injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	1	0	2
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
hypersensitivity			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 33 (0.00%)	0 / 124 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	2
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
dysmenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 33 (0.00%)	0 / 124 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 74 (0.00%)	0 / 298 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 33 (0.00%)	0 / 124 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	2
prostatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[5]	0 / 74 (0.00%)	1 / 298 (0.34%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 33 (0.00%)	1 / 124 (0.81%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	4 / 422 (0.95%)	0 / 91 (0.00%)
occurrences (all)	0	4	0
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	9 / 422 (2.13%)	2 / 91 (2.20%)
occurrences (all)	1	10	4
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
emphysema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	3 / 422 (0.71%)	1 / 91 (1.10%)
occurrences (all)	1	4	2
pulmonary mass			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	4 / 422 (0.95%)	1 / 91 (1.10%)
occurrences (all)	0	4	2
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0

tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	4 / 91 (4.40%)
occurrences (all)	0	0	8
depressed mood			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
irritability			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
tobacco abuse			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 107 (1.87%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	2	2	2
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	2	0
blood cholesterol increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	4
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 107 (2.80%)	3 / 422 (0.71%)	2 / 91 (2.20%)
occurrences (all)	3	3	4
blood glucose increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
blood pressure increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
blood triglycerides increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
blood urea increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
blood uric acid increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	1	2	0
c-reactive protein increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	1	2	0

heart rate increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
hepatitis b dna assay positive			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
liver function test abnormal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
liver function test increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
lymphocyte count decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
arthropod sting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 107 (1.87%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	2	1	2
epicondylitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 107 (2.80%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	3	1	0
foot fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	2 / 91 (2.20%)
occurrences (all)	0	0	6
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0

skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
dizziness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 107 (4.67%)	10 / 422 (2.37%)	2 / 91 (2.20%)
occurrences (all)	6	10	6
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
sciatica			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
leukocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
cataract			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
aphthous ulcer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
chronic gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
constipation			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
defaecation disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
dental caries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	8 / 422 (1.90%)	0 / 91 (0.00%)
occurrences (all)	0	9	0
dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
enteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
faeces soft			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
food poisoning			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0

gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
gastrointestinal disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
gingival atrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	1	1	6
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 107 (1.87%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	3	1	2
dermatitis psoriasiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
dyshidrotic eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0

eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
eczema asteatotic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
ingrowing nail			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
intertrigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 107 (2.80%)	5 / 422 (1.18%)	4 / 91 (4.40%)
occurrences (all)	3	5	8
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	1	2	2
rash			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	4 / 422 (0.95%)	2 / 91 (2.20%)
occurrences (all)	0	6	6
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 107 (2.80%)	10 / 422 (2.37%)	5 / 91 (5.49%)
occurrences (all)	3	11	12
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	1	0	2
arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 107 (1.87%)	3 / 422 (0.71%)	3 / 91 (3.30%)
occurrences (all)	2	3	6
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
costochondritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
enthesopathy			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
groin pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
joint effusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	2	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
muscle tightness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0

musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
pain in extremity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	2	0	2
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	2 / 422 (0.47%)	1 / 91 (1.10%)
occurrences (all)	1	2	2
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	4
Infections and infestations			
abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
acne pustular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
acute sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
bacteriuria			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
borrelia infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
carbuncle			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
chronic sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
conjunctivitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0

cystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
enterocolitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
epididymitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[7]	0 / 74 (0.00%)	1 / 298 (0.34%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
erythema migrans			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	5 / 422 (1.18%)	0 / 91 (0.00%)
occurrences (all)	0	5	0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	4 / 422 (0.95%)	0 / 91 (0.00%)
occurrences (all)	1	4	0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
hepatitis a			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
hepatitis e			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
hordeolum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
infected dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	3 / 91 (3.30%)
occurrences (all)	0	2	6

laryngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
molluscum contagiosum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	14 / 107 (13.08%)	55 / 422 (13.03%)	15 / 91 (16.48%)
occurrences (all)	14	61	35
onychomycosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	1	0	2
oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	4 / 422 (0.95%)	0 / 91 (0.00%)
occurrences (all)	0	4	0
otitis media			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
otitis media acute			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
paronychia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
parotitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
pelvic inflammatory disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[8]	0 / 33 (0.00%)	0 / 124 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	1	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 107 (2.80%)	7 / 422 (1.66%)	0 / 91 (0.00%)
occurrences (all)	3	7	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	1	3	0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0

respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	2 / 422 (0.47%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 33 (0.00%)	0 / 124 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
tinea pedis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
tinea versicolour			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
tonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	1 / 91 (1.10%)
occurrences (all)	0	1	2
tooth infection			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
tracheitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
typhoid fever			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	16 / 422 (3.79%)	7 / 91 (7.69%)
occurrences (all)	0	20	17
urethritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	8 / 422 (1.90%)	1 / 91 (1.10%)
occurrences (all)	1	10	2
vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 33 (0.00%)	1 / 124 (0.81%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 33 (0.00%)	1 / 124 (0.81%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	2
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	2 / 91 (2.20%)
occurrences (all)	0	0	3
gout			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	3 / 422 (0.71%)	1 / 91 (1.10%)
occurrences (all)	0	3	2
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	1	1	0
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 107 (1.87%)	3 / 422 (0.71%)	0 / 91 (0.00%)
occurrences (all)	2	3	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	5 / 422 (1.18%)	0 / 91 (0.00%)
occurrences (all)	1	5	0
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	1 / 422 (0.24%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 107 (0.00%)	0 / 422 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 107 (0.93%)	5 / 422 (1.18%)	0 / 91 (0.00%)
occurrences (all)	1	5	0

Non-serious adverse events	250 mg Miri Q4W Responders to 125 mg Miri Q8W	250 mg Miri Q4W Responder to 250 mg Miri Q8W	250mg Miri Q4W to 250mg Miri Q8W(Miri Non-Responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 90 (67.78%)	55 / 91 (60.44%)	0 / 140 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
fibroma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 90 (3.33%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	4	2	0
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
fat necrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
injection site induration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
injection site pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 90 (5.56%)	6 / 91 (6.59%)	0 / 140 (0.00%)
occurrences (all)	49	65	0
injection site pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	3	1	0
injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	1	2	0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0

pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	1 / 26 (3.85%)	1 / 32 (3.13%)	0 / 34 (0.00%)
occurrences (all)	1	2	0
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 64 (0.00%)	1 / 59 (1.69%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[5]	0 / 64 (0.00%)	0 / 59 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	4 / 91 (4.40%)	0 / 140 (0.00%)
occurrences (all)	2	4	0
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
emphysema			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	1	2	0
pulmonary mass			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0

vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tobacco abuse			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	1	2	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	1	4	0
blood cholesterol increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	3	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	2	0
blood urea increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
c-reactive protein increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	1	2	0
heart rate increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
hepatitis b dna assay positive alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

liver function test abnormal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
weight decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	2	2	0
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
arthropod sting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0
epicondylitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	0	2	0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	3	0	0
post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	2	0
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0

wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
palpitations			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dizziness			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 90 (5.56%)	4 / 91 (4.40%)	0 / 140 (0.00%)
occurrences (all)	9	5	0
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
sciatica			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
vertigo			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
defaecation disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	0	3	0

dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
gingival atrophy			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
glossitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
stomatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	2	2	0
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
cholelithiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dermal cyst			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
dermatitis contact			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 90 (3.33%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	3	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
ingrowing nail			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
intertrigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	3	2	0
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 90 (3.33%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	3	3	0
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 90 (4.44%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	4	2	0
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
joint effusion			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
joint swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
muscle tightness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
muscular weakness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	2	1	0

pain in extremity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
acne pustular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
acute sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
bacteriuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
body tinea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
borrelia infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	2	4	0
carbuncle			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
cystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
enterocolitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[7]	0 / 64 (0.00%)	0 / 59 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0

erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
folliculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	2	2	0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	0	3	0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
herpes zoster			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
hordeolum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	3 / 91 (3.30%)	0 / 140 (0.00%)
occurrences (all)	0	3	0
laryngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	13 / 90 (14.44%)	9 / 91 (9.89%)	0 / 140 (0.00%)
occurrences (all)	16	13	0
onychomycosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	5	1	0
otitis media			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
otitis media acute			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0
parotitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
pelvic inflammatory disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[8]	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
periodontitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 90 (3.33%)	4 / 91 (4.40%)	0 / 140 (0.00%)
occurrences (all)	3	4	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0

subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
tooth infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
tracheitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
typhoid fever			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 90 (5.56%)	10 / 91 (10.99%)	0 / 140 (0.00%)
occurrences (all)	5	11	0
urethritis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 90 (3.33%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	3	2	0
vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 90 (0.00%)	2 / 91 (2.20%)	0 / 140 (0.00%)
occurrences (all)	0	2	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	2	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	0	0	0
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 140 (0.00%)
occurrences (all)	1	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	0 / 140 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Placebo Q4W to Placebo Q8W (Placebo Responder)	Placebo Q4W to 250 mg Miri Q4W /Q8W (Placebo Non-Responders)	Relapse
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	17 / 47 (36.17%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fibroma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fat necrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 67 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 67 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
emphysema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tobacco abuse			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood urea increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
c-reactive protein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hepatitis b dna assay positive			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
lymphocyte count decreased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
ligament sprain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
defaecation disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

enteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gingival atrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
ingrowing nail			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
back pain			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
joint effusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
muscle tightness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1

plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
acne pustular			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
acute sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
bacteriuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
borrelia infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
carbuncle			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

chronic sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
enterocolitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 67 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

hordeolum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
onychomycosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
otitis media acute			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
parotitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pelvic inflammatory disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[8]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
pharyngotonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
tracheitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
typhoid fever			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
urethritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1

vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 4 (0.00%)	0 / 27 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 4 (0.00%)	0 / 27 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 94 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo Q4W Discontinued During Induction-Follow-up Period	250 Miri Q4W Discontinued During Induction-Follow-up	250 mg Miri Q4W to Placebo Q8W (Responders) Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fibroma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fat necrosis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
emphysema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tobacco abuse			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood pressure increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood urea increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
c-reactive protein increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

heart rate increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatitis b dna assay positive			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
defaecation disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gingival atrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ingrowing nail			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
joint effusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
acne pustular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
acute sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bacteriuria			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
borrelia infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
carbuncle			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

cystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
enterocolitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

laryngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
onychomycosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
otitis media acute			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
parotitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pelvic inflammatory disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[8]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
tracheitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
typhoid fever			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urethritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	250mg Miri Q4W to 125 mg Miri Q8W(Responders) Follow-up Period	250mg Miri Q4W to 250mg Miri Q8W(Responders) Follow-up Period	250 miri Q4W to Miri nonresponder-Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fibroma			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
haematoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fat necrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site induration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[5]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
emphysema			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pulmonary mass			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tobacco abuse			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood pressure increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood urea increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
c-reactive protein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fibrin d dimer increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatitis b dna assay positive			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

liver function test abnormal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
liver function test increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
arthropod sting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
epicondylitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
foot fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
palpitations			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dizziness			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cataract			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
aphthous ulcer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
chronic gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
defaecation disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
enteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
faeces soft			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gingival atrophy			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
glossitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermal cyst			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermatitis psoriasiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ingrowing nail			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
intertrigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
costochondritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
enthesopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
joint effusion			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
muscle tightness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
muscular weakness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

pain in extremity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
acne pustular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
acute sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bacteriuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
body tinea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
borrelia infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
carbuncle			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
chronic sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
enterocolitis bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
epididymitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[7]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastrointestinal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatitis a			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
infected dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
onychomycosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
otitis media acute			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
parotitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pelvic inflammatory disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[8]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
periodontitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pharyngotonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tinea versicolour			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tracheitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
typhoid fever			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
urethritis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo Q4W to Placebo Q8W (Placebo Responder) - Follow-up	Placebo Q4W to Placebo Non-Responder-Follow-up Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
basal cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dysplastic naevus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
fibroma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
lipoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
skin papilloma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
blood pressure fluctuation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

essential hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
haematoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
varicose vein			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
duodenal sphincterotomy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tooth extraction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
wisdom teeth removal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			

chest pain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
fat necrosis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
fatigue				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
hyperthermia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
influenza like illness				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
injection site erythema				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
injection site induration				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
injection site pain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
injection site pruritus				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
injection site reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
injection site swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
malaise			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
xerosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
drug hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
breast pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dysmenorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
erectile dysfunction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[3]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
menstruation irregular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[4]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
prostatitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed[5]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vaginal discharge			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[6]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
emphysema			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
nasal congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pulmonary mass			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rhinitis allergic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rhinorrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tonsillar hypertrophy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
upper-airway cough syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vocal cord polyp			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
depressed mood			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
irritability			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
libido decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
sleep disorder			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tobacco abuse			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood cholesterol increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood creatine phosphokinase increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood glucose increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood pressure increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood triglycerides increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood urea increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
blood uric acid increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
c-reactive protein increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

electrocardiogram qt prolonged				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
fibrin d dimer increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
heart rate increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
hepatic enzyme increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
hepatitis b dna assay positive				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
liver function test abnormal				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
liver function test increased				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
lymphocyte count decreased				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
thyroxine free decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
very low density lipoprotein increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
weight decreased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
weight increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
white blood cell count increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
arthropod bite			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
arthropod sting				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
contusion				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
epicondylitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
fall				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
foot fracture				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
ligament sprain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
limb injury				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
meniscus injury				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

post concussion syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
procedural pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rib fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
skin abrasion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
skin laceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
thermal burn			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
wound			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
wound complication			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			

acute myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
bradycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cardiac failure chronic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
palpitations			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
cerebral infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cervical radiculopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dizziness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
facial paralysis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypoaesthesia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
migraine			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
sciatica			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
sinus headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
somnolence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
hilar lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
leukocytosis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
lymphadenopathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
thrombocytosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
ear pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vertigo			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cataract			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cataract subcapsular			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
conjunctival haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
ocular hyperaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
visual impairment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vitreous floaters			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
abdominal pain lower			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
abdominal pain upper			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
aphthous ulcer				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
chronic gastritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
constipation				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
defaecation disorder				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
dental caries				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
diarrhoea				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
dry mouth				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
dyspepsia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

enteritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
faeces soft				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
food poisoning				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastrointestinal disorder				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gingival atrophy				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
glossitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
haemorrhoids				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
periodontal disease			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
stomatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
toothache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
umbilical hernia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
cholelithiasis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hepatic steatosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
actinic keratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
alopecia areata			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
blister			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dermal cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dermatitis contact			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
dermatitis psoriasiform				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
diffuse alopecia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
dyshidrotic eczema				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
eczema				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
eczema asteatotic				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
erythema				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
ingrowing nail				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
intertrigo				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

perioral dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
psoriasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rash			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rosacea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
skin fissures			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			

dysuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pollakiuria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypothyroidism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
arthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
back pain			

alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
bursitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
costochondritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
enthesopathy				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
fasciitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
groin pain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
intervertebral disc protrusion				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
joint effusion				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
joint swelling				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
muscle spasms				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
muscle tightness				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
muscular weakness				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
musculoskeletal chest pain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
musculoskeletal pain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
myalgia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
osteoarthritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
pain in extremity				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

plantar fasciitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
psoriatic arthropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rotator cuff syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
spinal osteoarthritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
spinal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
synovial cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tendonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
abdominal wall abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
acne pustular			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
acute sinusitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
bacterial infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
bacteriuria				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
body tinea				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
borrelia infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
bronchitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
carbuncle				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
cellulitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

chronic sinusitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
conjunctivitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
conjunctivitis bacterial				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
cystitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
ear infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
enterocolitis bacterial				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
epididymitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed[7]	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
erysipelas				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
erythema migrans				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
folliculitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastroenteritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastroenteritis viral				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
gastrointestinal infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
helicobacter gastritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
hepatitis a				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
hepatitis e				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
herpes zoster				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

hordeolum				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
infected dermal cyst				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
influenza				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
laryngitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
molluscum contagiosum				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
nasopharyngitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
onychomycosis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
oral herpes				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
otitis media				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
otitis media acute				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
paronychia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
parotitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
pelvic inflammatory disease				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed[8]	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
periodontitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
pharyngitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
pharyngitis streptococcal				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
pharyngotonsillitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
pulpitis dental			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
rhinitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
salpingo-oophoritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
subcutaneous abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
tinea pedis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
tinea versicolour				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
tonsillitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
tooth infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
tracheitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
typhoid fever				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
upper respiratory tract infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
urethritis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
urinary tract infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

vaginal infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[10]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
viral infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[11]	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
cardiometabolic syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
dyslipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
gout			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypercholesterolaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hyperlipidaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hypertriglyceridaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
hyperuricaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
increased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
overweight			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported