



## Clinical trial results:

### A Long-Term Extension Study to Demonstrate Safety of Tildrakizumab in Subjects with Psoriatic Arthritis who Have Previously Completed Study with Tildrakizumab

#### Summary

EudraCT number	2018-001060-35
Trial protocol	HU ES PL
Global end of trial date	18 September 2023

#### Results information

Result version number	v1 (current)
This version publication date	03 October 2024
First version publication date	03 October 2024

#### Trial information

##### Trial identification

Sponsor protocol code	CLR_18_07
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03552276
WHO universal trial number (UTN)	-

Notes:

##### Sponsors

Sponsor organisation name	Sun Pharmaceutical Industries Limited (SPIL)
Sponsor organisation address	17/B, Mahal Industries Limited, Mahakali Caves Road, Andheri(East), Mumbai, Mumbai, India,
Public contact	Shantanu Bhushankumar Mehta, General Manager, Sun Pharmaceutical Industries Limited (SPIL), Clinical.Trial@sunpharma.com
Scientific contact	Shantanu Bhushankumar Mehta, General Manager, Sun Pharmaceutical Industries Limited (SPIL), Clinical.Trial@sunpharma.com

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	18 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 September 2023
Global end of trial reached?	Yes
Global end of trial date	18 September 2023
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To assess the long-term safety of tildrakizumab when administered to PsA by evaluation of subjects:

- Incidence and intensity of all AEs,
- Changes in vital signs, laboratory assessments, electrocardiograms (ECGs), and Columbia-Suicide Severity Rating Scale (C-SSRS),
- Immunogenicity of multiple-dose administration of tildrakizumab in these subjects.

Protection of trial subjects:

The following measures were in place during the execution of the study to ensure safety and protection of trial subjects:

- All subjects underwent Screening procedures at the start of their parent study aimed at reducing the likelihood and impact of any risks.
- In addition, regular safety monitoring during the treatment period of the parent study and the long-term extension study for all subjects ensured that any unanticipated effects of study participation were identified promptly and managed appropriately.
- The design allowed withdrawal of subjects from tildrakizumab at the end of the parent study (in accordance with the current parent protocol wash-out phase) and at any time thereafter during the extension study if, in the opinion of the Investigator, the subject was no longer obtaining sufficient clinical benefit, thus enabling subjects to receive other treatment in accordance with local clinical practice.
- Clinical adjudication committee was established to monitor cardiovascular events

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 July 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 112
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	Hungary: 9
Country: Number of subjects enrolled	Argentina: 4
Country: Number of subjects enrolled	Mexico: 33
Country: Number of subjects enrolled	Russian Federation: 30
Country: Number of subjects enrolled	Ukraine: 32
Country: Number of subjects enrolled	United States: 38

Worldwide total number of subjects	281
EEA total number of subjects	144

Notes:

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**Subjects enrolled per age group**

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	247
From 65 to 84 years	33
85 years and over	1

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

In total 303 subjects were screened, of which 19 subjects were screen failures. Of the 281 treated subjects, 205 subjects completed treatment, and 76 subjects were discontinued from the study. The most frequent reasons for discontinuation from study were withdrawal of consent in 41 subjects, adverse event in 17 subjects, and Other in 7 subjects

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

This study is open label, long term extension (LTE) study of CLR 16-23. Subjects continued in the LTE with the same treatment group as the parent study ( CLR 16-23) until all the subjects in the parent study rolled over to the LTE and blinding was no longer needed.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Tildrakizumab 200 mg, q4 weeks

Arm description: -

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

Dosage and administration details:

Tildrakizumab 200 mg administered by SC injection q4 weeks

<b>Arm title</b>	Tildrakizumab 200 mg, q12 weeks
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Arm description: -

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

Dosage and administration details:

Tildrakizumab 200 mg administered by SC injection q12 weeks

<b>Arm title</b>	Tildrakizumab 100 mg, q12 weeks
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Arm description: -

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

Dosage and administration details:

Tildrakizumab 100 mg administered by SC injection q12 weeks

<b>Arm title</b>	Tildra 200 mg, q4 weeks switched to 100 mg Tildra q12 weeks
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Arm description: -

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

Dosage and administration details:

The subjects who received Tildrakizumab 200 mg, q4 weeks, in the parent study switched to Tildrakizumab 100 mg administered by SC injection q12 weeks therefore

<b>Arm title</b>	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks
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Arm description: -

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

Dosage and administration details:

The subjects who received Tildrakizumab 200 mg, q12 weeks in the parent study switched to Tildrakizumab 100 mg administered by SC injection q12 weeks in this study

<b>Number of subjects in period 1</b>	Tildrakizumab 200 mg, q4 weeks	Tildrakizumab 200 mg, q12 weeks	Tildrakizumab 100 mg, q12 weeks
Started	5	22	49
Completed	0	0	33
Not completed	5	22	16
Subject Non-Compliance	-	-	-
Consent withdrawn by subject	1	10	8
Adverse event, non-fatal	3	5	4
Other	1	2	1
Sponsor Decision	-	2	2
Lost to follow-up	-	1	-
Lack of efficacy	-	2	1

<b>Number of subjects in period 1</b>	Tildra 200 mg, q4 weeks switched to 100 mg Tildra q12 weeks	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks
Started	54	151
Completed	46	126
Not completed	8	25
Subject Non-Compliance	1	-
Consent withdrawn by subject	4	18
Adverse event, non-fatal	2	3
Other	1	2
Sponsor Decision	-	-
Lost to follow-up	-	1
Lack of efficacy	-	1

## Baseline characteristics

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### Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

<b>Reporting group values</b>	Overall Study	Total	
Number of subjects	281	281	
Age categorical Units: Subjects			
Adults (18-64 years)	247	247	
From 65-84 years	33	33	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	152	152	
Male	129	129	

## End points

### End points reporting groups

Reporting group title	Tildrakizumab 200 mg, q4 weeks
Reporting group description: -	
Reporting group title	Tildrakizumab 200 mg, q12 weeks
Reporting group description: -	
Reporting group title	Tildrakizumab 100 mg, q12 weeks
Reporting group description: -	
Reporting group title	Tildra 200 mg, q4 weeks switched to 100 mg Tildra q12 weeks
Reporting group description: -	
Reporting group title	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks
Reporting group description: -	

### Primary: Number of Participants With Adverse Events and Its Relationship to Investigational Medicinal Product Will be Assessed by the Investigator (Global Introspection Assessment) [Time Frame: upto week 208]

End point title	Number of Participants With Adverse Events and Its Relationship to Investigational Medicinal Product Will be Assessed by the Investigator (Global Introspection Assessment) [Time Frame: upto week 208] <sup>[1]</sup>
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End point description:

End point type	Primary
End point timeframe: Week 208	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Safety endpoints were analyzed descriptively and analysis was based on the treatment subjects actually received

End point values	Tildrakizumab 200 mg, q4 weeks	Tildrakizumab 200 mg, q12 weeks	Tildrakizumab 100 mg, q12 weeks	Tildra 200 mg, q4 weeks switched to 100 mg Tildra q12 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	22	49	54
Units: Number of Subjects	5	14	36	44

End point values	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks			
Subject group type	Reporting group			
Number of subjects analysed	151			
Units: Number of Subjects	125			

## **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Week 208

Adverse event reporting additional description:

The "non -serious adverse events" described in the table are all the "treatment emergent adverse events" reported in the study

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	26

### Reporting groups

Reporting group title	Tildrakizumab 200 mg, q4 weeks
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Reporting group description: -

Reporting group title	Tildrakizumab 200 mg, q12 weeks
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Reporting group description: -

Reporting group title	Tildrakizumab 100 mg, q12 weeks
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Reporting group description: -

Reporting group title	Tildra 200 mg, q4 weeks switched to Tildra 100 mg, q12 weeks
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Reporting group description: -

Reporting group title	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks
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Reporting group description: -

<b>Serious adverse events</b>	Tildrakizumab 200 mg, q4 weeks	Tildrakizumab 200 mg, q12 weeks	Tildrakizumab 100 mg, q12 weeks
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	2 / 22 (9.09%)	7 / 49 (14.29%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal carcinoma</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Uterine leiomyoma</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular disorders</b>			
<b>Aortic dissection</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Arteriosclerosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Deep vein thrombosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypertension</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypertensive crisis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Surgical and medical procedures</b>			

Gastric bypass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Hydrocele female			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Biopsy kidney			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Craniocerebral injury			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
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			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (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
Tibia fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
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			
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal migraine			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (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			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (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
Tension headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Musculoskeletal and connective tissue disorders</b>			
Intervertebral disc disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Abdominal abscess			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

	Tildra 200 mg, q4 weeks switched to Tildra 100 mg, q12 weeks	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks	
<b>Serious adverse events</b>			
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 54 (5.56%)	25 / 151 (16.56%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal adenoma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			

subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine leiomyoma</b>			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			
<b>Aortic dissection</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arteriosclerosis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Deep vein thrombosis</b>			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypertension</b>			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypertensive crisis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Surgical and medical procedures</b>			
<b>Gastric bypass</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>General disorders and administration</b>			

site conditions			
Generalised oedema			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Hydrocele female			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Biopsy kidney			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Humerus fracture</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ligament rupture</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Subdural haematoma</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tibia fracture</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
<b>Acute myocardial infarction</b>			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac failure</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coronary artery stenosis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tachycardia</b>			

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
Dizziness			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal migraine			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
Anaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
Abdominal hernia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haemorrhagic erosive gastritis subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders Cholelithiasis subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders Acute kidney injury subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders Intervertebral disc disorder			

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Lumbar spinal stenosis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Osteoarthritis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rhabdomyolysis</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>COVID-19 pneumonia</b>			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gallbladder empyema</b>			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Intestinal sepsis</b>			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Septic shock</b>			

subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (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 %

<b>Non-serious adverse events</b>	Tildrakizumab 200 mg, q4 weeks	Tildrakizumab 200 mg, q12 weeks	Tildrakizumab 100 mg, q12 weeks
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	14 / 22 (63.64%)	36 / 49 (73.47%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Adrenal adenoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Anogenital warts			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Benign oesophageal neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Colorectal adenoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Haemangioma of liver			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Oesophageal carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Prostatic adenoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Vascular disorders</b>			
Aortic arteriosclerosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Aortic dissection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Arteriosclerosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Bleeding varicose vein			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood pressure fluctuation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diabetic microangiopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Essential hypertension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 3	0 / 22 (0.00%) 0	2 / 49 (4.08%) 2
Hypertensive crisis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Lymphostasis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Peripheral venous disease subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Surgical and medical procedures Gastric bypass subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Chest pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Drug intolerance			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Injection site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
Vaccination site pain			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Xerosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 1	0 / 49 (0.00%) 0
Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Allergy to plants subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Reproductive system and breast disorders Abnormal uterine bleeding subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Adenomyosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Bartholin's cyst subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 1	0 / 49 (0.00%) 0
Hydrocele female subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 1	0 / 49 (0.00%) 0
Prostatitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Uterine haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	0 / 49 (0.00%)
occurrences (all)	0	2	0

Irritability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	1	0	4
Apolipoprotein B increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bilirubin urine present			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Biopsy kidney			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Blood cholesterol increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	3
Blood creatinine increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	3
Blood pressure increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	1	0	3
Blood triglycerides increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	3
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Low density lipoprotein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Monocyte count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 5
Prostatic specific antigen increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Red blood cell count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 2
Transaminases increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Urinary casts subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 1	0 / 49 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Injury, poisoning and procedural complications			

Burns second degree			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Concussion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Craniocerebral injury			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Cuboid syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
Fibula fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hip fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Iliotibial band syndrome			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Immunisation reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Post vaccination syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0

Soft tissue injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Synovial rupture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tibia fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 22 (4.55%)	2 / 49 (4.08%)
occurrences (all)	1	2	3
Bilirubin conjugated increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Accessory spleen			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gilbert's syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Atrioventricular block first degree			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Coronary artery stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Diastolic dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Pericardial cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bradykinesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Headache			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Metabolic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Myotonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Neuritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Parkinson's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Sensory loss			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Spinal cord haematoma</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Subarachnoid haemorrhage</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
<b>Syncope</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Tension headache</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Retinal migraine</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	3	0
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	3
<b>Leukocytosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Leukopenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Lymphadenopathy</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Lymphopenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Neutropenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Neutrophilia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Eye disorders Astigmatism subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Blepharitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Blindness transient subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 2	0 / 49 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Cataract nuclear subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Diabetic retinopathy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	1 / 49 (2.04%) 1
Keratitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Myopia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Retinal vascular disorder			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Gastrointestinal disorders</b>			
Abdominal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	4 / 49 (8.16%)
occurrences (all)	0	0	4
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Abdominal rigidity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Barrett's oesophagus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Chronic gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Coeliac artery stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
Diaphragmatic hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	4 / 22 (18.18%)	3 / 49 (6.12%)
occurrences (all)	0	6	5
Diverticulum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diverticulum intestinal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Duodenitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Gastritis erosive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Intestinal metaplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	3
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	2 / 22 (9.09%)	2 / 49 (4.08%)
occurrences (all)	1	2	2
Pancreatitis chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Rectal polyp			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Retained deciduous tooth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cholecystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Cholestasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diabetic hepatopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Gallbladder polyp			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Hepatitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Hyperbilirubinaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	3	1
<b>Hypertransaminasaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
<b>Non-alcoholic steatohepatitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Steatohepatitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Skin and subcutaneous tissue disorders</b>			
<b>Alopecia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Angioedema</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Ecchymosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Erythema</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Hidradenitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Pruritus</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Psoriasis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2

Rash			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Calculus urinary			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
End stage renal disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Glomerulonephritis chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			

subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
<b>Nephrolithiasis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Nephrosclerosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Pollakiuria</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Proteinuria</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Renal colic</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Renal cyst</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Stress urinary incontinence</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Ureterolithiasis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Urinary tract inflammation</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Endocrine disorders</b>			
<b>Autoimmune thyroiditis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Goitre</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Hypothyroidic goitre			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Thyroid mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 22 (13.64%)	1 / 49 (2.04%)
occurrences (all)	0	3	1
Arthritis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	4 / 49 (8.16%)
occurrences (all)	0	0	5
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dactylitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Fracture pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc disorder			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc displacement			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Jaw cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Joint contracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Metatarsalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	2 / 49 (4.08%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	3
Osteochondrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Periarticular disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pseudarthrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	1 / 49 (2.04%)
occurrences (all)	0	3	2
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Sacroiliitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
<b>Spinal disorder</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Spinal osteoarthritis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Spinal pain</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Spinal stenosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
<b>Spondylolisthesis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Synovial cyst</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Tendonitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	2 / 49 (4.08%)
occurrences (all)	0	2	2
<b>Tenosynovitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Tenosynovitis stenosans</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Trigger finger</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
<b>Infections and infestations</b>			

Abdominal abscess			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Acute sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bartholin's abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0

Coronavirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Erythema migrans			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Escherichia infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gallbladder empyema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Helicobacter gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Intestinal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Joint abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	7 / 49 (14.29%)
occurrences (all)	0	1	8

Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Pyelonephritis acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tracheobronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 22 (4.55%) 1	7 / 49 (14.29%) 8
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 22 (4.55%) 3	2 / 49 (4.08%) 3
Vaginal infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Metabolism and nutrition disorders			
Cholesterosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Copper deficiency subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	0 / 49 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 22 (0.00%) 0	2 / 49 (4.08%) 2
Diabetes mellitus			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 5 (0.00%)	1 / 22 (4.55%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Dyslipidaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 22 (9.09%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
Hyperglycaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	1	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Impaired fasting glucose			

subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
Vitamin D deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 22 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

<b>Non-serious adverse events</b>	Tildra 200 mg, q4 weeks switched to Tildra 100 mg, q12 weeks	Tildra 200 mg, q12 weeks switched to Tildra 100 mg, q12 weeks	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 54 (81.48%)	125 / 151 (82.78%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Adrenal adenoma			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Anogenital warts			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Benign oesophageal neoplasm			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Colorectal adenoma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Haemangioma of liver			

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Oesophageal carcinoma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Prostatic adenoma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Uterine leiomyoma			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
<b>Vascular disorders</b>			
Aortic arteriosclerosis			
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)	
occurrences (all)	1	2	
Aortic dissection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Arteriosclerosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Bleeding varicose vein			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Blood pressure fluctuation			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Deep vein thrombosis			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Diabetic microangiopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	

Essential hypertension subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Hypertension subjects affected / exposed occurrences (all)	5 / 54 (9.26%) 6	10 / 151 (6.62%) 12	
Hypertensive crisis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Lymphostasis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Peripheral venous disease subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	2 / 151 (1.32%) 2	
Phlebitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Surgical and medical procedures Gastric bypass subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 151 (1.32%) 2	
Chest pain subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	2 / 151 (1.32%) 3	
Chills subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
Drug intolerance			

subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Fatigue		
subjects affected / exposed	0 / 54 (0.00%)	4 / 151 (2.65%)
occurrences (all)	0	4
Generalised oedema		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Influenza like illness		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Injection site erythema		
subjects affected / exposed	2 / 54 (3.70%)	1 / 151 (0.66%)
occurrences (all)	10	1
Injection site pain		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Injection site pruritus		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	2	0
Injection site rash		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Injection site reaction		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Injury associated with device		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Oedema peripheral		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2
Pyrexia		
subjects affected / exposed	4 / 54 (7.41%)	4 / 151 (2.65%)
occurrences (all)	5	5
Vaccination site pain		

subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Xerosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	3 / 151 (1.99%) 3	
Allergy to plants subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Reproductive system and breast disorders Abnormal uterine bleeding subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 2	
Adenomyosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Bartholin's cyst subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Hydrocele female subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Prostatitis			

subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Prostatomegaly subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Uterine haemorrhage subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Cough subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	2 / 151 (1.32%) 3	
Dysphonia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Interstitial lung disease subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Nasal congestion subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Respiratory failure subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Rhinorrhoea			

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Sinus congestion			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Dermatitis allergic			
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)	
occurrences (all)	1	1	
Dermatitis contact			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Dermatitis psoriasiform			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Affective disorder			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Anxiety			
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)	
occurrences (all)	1	1	
Depression			
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)	
occurrences (all)	0	3	
Insomnia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	2	

Irritability			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Mixed anxiety and depressive disorder			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Sleep disorder			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Stress			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 54 (3.70%)	3 / 151 (1.99%)	
occurrences (all)	2	3	
Apolipoprotein B increased			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Bilirubin urine present			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Biopsy kidney			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Blood bilirubin increased			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Blood cholesterol increased			
subjects affected / exposed	2 / 54 (3.70%)	3 / 151 (1.99%)	
occurrences (all)	2	3	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)	
occurrences (all)	1	3	
Blood creatinine increased			

subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Blood glucose increased		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Blood pressure increased		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	3
Blood triglycerides increased		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	3
Blood urea increased		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
C-reactive protein increased		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 54 (1.85%)	5 / 151 (3.31%)
occurrences (all)	1	6
Glomerular filtration rate decreased		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Haematocrit decreased		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Haemoglobin decreased		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Hepatic enzyme increased		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Low density lipoprotein increased		
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)
occurrences (all)	1	4

Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Monocyte count decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Prostatic specific antigen increased subjects affected / exposed occurrences (all)	2 / 54 (3.70%) 2	0 / 151 (0.00%) 0	
Red blood cell count decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Transaminases increased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Urinary casts subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Weight decreased subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Weight increased subjects affected / exposed occurrences (all)	3 / 54 (5.56%) 3	7 / 151 (4.64%) 7	
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Injury, poisoning and procedural complications			

Burns second degree		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Concussion		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Contusion		
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)
occurrences (all)	0	3
Craniocerebral injury		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Cuboid syndrome		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Epicondylitis		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Fall		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Fibula fracture		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Foot fracture		
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)
occurrences (all)	0	3
Hand fracture		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Hip fracture		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Humerus fracture		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1

Iliotibial band syndrome		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Immunisation reaction		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Joint injury		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Ligament rupture		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2
Ligament sprain		
subjects affected / exposed	2 / 54 (3.70%)	4 / 151 (2.65%)
occurrences (all)	2	4
Limb injury		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Meniscus injury		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2
Muscle strain		
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)
occurrences (all)	0	3
Nail avulsion		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Post vaccination syndrome		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	2
Skin abrasion		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2
Skin laceration		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0

Soft tissue injury			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Spinal compression fracture			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Subdural haematoma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Synovial rupture			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Tendon injury			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Thermal burn			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Tibia fracture			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	2	
Tooth fracture			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)	
occurrences (all)	1	3	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Accessory spleen			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Gilbert's syndrome			

subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Hydrocele subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Atrioventricular block first degree subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
Acute myocardial infarction subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 151 (1.32%) 2	
Cardiac failure subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Cardiac failure congestive subjects affected / exposed occurrences (all)	2 / 54 (3.70%) 2	1 / 151 (0.66%) 1	
Coronary artery stenosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Diastolic dysfunction subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Mitral valve incompetence subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 151 (1.32%) 2	
Myocardial ischaemia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Palpitations subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	

Pericardial cyst			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Sinus tachycardia			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	2	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Bradykinesia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)	
occurrences (all)	1	2	
Cervicobrachial syndrome			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Diabetic neuropathy			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	3	
Encephalopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Headache			

subjects affected / exposed	4 / 54 (7.41%)	13 / 151 (8.61%)
occurrences (all)	6	37
Hypoaesthesia		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Lumbar radiculopathy		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Metabolic encephalopathy		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Migraine		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Myotonia		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Neuralgia		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Neuritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Parkinson's disease		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Restless legs syndrome		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Sciatica		
subjects affected / exposed	1 / 54 (1.85%)	4 / 151 (2.65%)
occurrences (all)	1	5
Sensory loss		

subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Spinal cord haematoma			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Tension headache			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Retinal migraine			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)	
occurrences (all)	0	3	
Leukocytosis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Lymphadenopathy			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Lymphopenia			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Neutropenia			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	3	

Neutrophilia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Vertigo subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
Eye disorders Astigmatism subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Blepharitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Blindness transient subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Cataract subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 151 (1.32%) 2	
Cataract nuclear subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Diabetic retinopathy subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Keratitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Myopia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Retinal vascular disorder			

subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Visual acuity reduced subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
<b>Gastrointestinal disorders</b>			
Abdominal hernia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Abdominal pain subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Abdominal rigidity subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 2	
Anal fistula subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Barrett's oesophagus subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Chronic gastritis subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
Coeliac artery stenosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Constipation subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	

Dental caries		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Diaphragmatic hernia		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Diarrhoea		
subjects affected / exposed	4 / 54 (7.41%)	6 / 151 (3.97%)
occurrences (all)	5	8
Diverticulum		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Diverticulum intestinal		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Duodenitis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Dyspepsia		
subjects affected / exposed	2 / 54 (3.70%)	0 / 151 (0.00%)
occurrences (all)	3	0
Enteritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Food poisoning		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gastric ulcer		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gastritis		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Gastritis erosive		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0

Gastrointestinal disorder		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 54 (3.70%)	0 / 151 (0.00%)
occurrences (all)	2	0
Gingival swelling		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Haemorrhagic erosive gastritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	2
Haemorrhoids		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2
Hiatus hernia		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Intestinal metaplasia		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Intestinal obstruction		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Irritable bowel syndrome		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	2
Large intestine polyp		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Nausea		
subjects affected / exposed	0 / 54 (0.00%)	6 / 151 (3.97%)
occurrences (all)	0	16
Pancreatitis chronic		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1

Rectal polyp			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Retained deciduous tooth			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Toothache			
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)	
occurrences (all)	3	5	
Vomiting			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Cholecystitis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	3	
Cholelithiasis			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	2	0	
Cholestasis			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Diabetic hepatopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gallbladder polyp			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Hepatic steatosis			
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)	
occurrences (all)	0	3	
Hepatitis			

subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 151 (1.32%) 2	
Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Non-alcoholic steatohepatitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Steatohepatitis subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
<b>Skin and subcutaneous tissue disorders</b>			
Alopecia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Angioedema subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Ecchymosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Erythema subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Hidradenitis subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
Pruritus subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Psoriasis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	5 / 151 (3.31%) 5	

Rash			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	2	
Skin exfoliation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Calculus urinary			
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)	
occurrences (all)	0	5	
Chronic kidney disease			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Cystitis haemorrhagic			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Cystitis noninfective			
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)	
occurrences (all)	1	1	
End stage renal disease			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	2	
Glomerulonephritis chronic			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Hypertonic bladder			

subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
<b>Nephrolithiasis</b>			
subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
<b>Nephrosclerosis</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
<b>Pollakiuria</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
<b>Proteinuria</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
<b>Renal colic</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	3 / 151 (1.99%) 3	
<b>Renal cyst</b>			
subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	1 / 151 (0.66%) 1	
<b>Stress urinary incontinence</b>			
subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
<b>Ureterolithiasis</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
<b>Urinary tract inflammation</b>			
subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	
<b>Endocrine disorders</b>			
<b>Autoimmune thyroiditis</b>			
subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
<b>Goitre</b>			
subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	0 / 151 (0.00%) 0	

Hypothyroidic goitre			
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Thyroid mass			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 54 (1.85%)	6 / 151 (3.97%)	
occurrences (all)	1	7	
Arthritis			
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)	
occurrences (all)	1	2	
Back pain			
subjects affected / exposed	2 / 54 (3.70%)	6 / 151 (3.97%)	
occurrences (all)	2	9	
Bursitis			
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)	
occurrences (all)	0	4	
Dactylitis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Exostosis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Fracture pain			
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)	
occurrences (all)	0	1	
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Intervertebral disc disorder			

subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	3
Intervertebral disc displacement		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Intervertebral disc protrusion		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Jaw cyst		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	2
Joint contracture		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	3	0
Joint effusion		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	3
Joint swelling		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Lumbar spinal stenosis		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Metatarsalgia		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Muscle spasms		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Musculoskeletal discomfort		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Musculoskeletal stiffness		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Myalgia		

subjects affected / exposed	2 / 54 (3.70%)	2 / 151 (1.32%)
occurrences (all)	3	2
Neck pain		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Osteoarthritis		
subjects affected / exposed	2 / 54 (3.70%)	2 / 151 (1.32%)
occurrences (all)	4	2
Osteochondrosis		
subjects affected / exposed	2 / 54 (3.70%)	1 / 151 (0.66%)
occurrences (all)	2	2
Osteoporosis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Pain in extremity		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	3
Periarthritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Periarticular disorder		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Plantar fasciitis		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Pseudarthrosis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Psoriatic arthropathy		
subjects affected / exposed	1 / 54 (1.85%)	9 / 151 (5.96%)
occurrences (all)	1	17
Rhabdomyolysis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Rotator cuff syndrome		

subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Sacroiliitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Spinal disorder		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Spinal osteoarthritis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Spinal pain		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Spinal stenosis		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Spondylolisthesis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Synovial cyst		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Tendonitis		
subjects affected / exposed	2 / 54 (3.70%)	0 / 151 (0.00%)
occurrences (all)	2	0
Tenosynovitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Tenosynovitis stenosans		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	2	1
Trigger finger		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Infections and infestations		

Abdominal abscess		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Acute sinusitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Adenovirus infection		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Bacteriuria		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Bartholin's abscess		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Breast abscess		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Bronchitis		
subjects affected / exposed	2 / 54 (3.70%)	1 / 151 (0.66%)
occurrences (all)	2	1
COVID-19		
subjects affected / exposed	11 / 54 (20.37%)	25 / 151 (16.56%)
occurrences (all)	12	29
COVID-19 pneumonia		
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)
occurrences (all)	0	3
Cellulitis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Chronic sinusitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Conjunctivitis		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	2	1

Coronavirus infection		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Cystitis		
subjects affected / exposed	0 / 54 (0.00%)	3 / 151 (1.99%)
occurrences (all)	0	3
Diverticulitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Erythema migrans		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Escherichia infection		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Furuncle		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gallbladder empyema		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gastroenteritis		
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)
occurrences (all)	1	3
Gastroenteritis viral		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Gastrointestinal bacterial overgrowth		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gastrointestinal infection		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Gingivitis		
subjects affected / exposed	0 / 54 (0.00%)	2 / 151 (1.32%)
occurrences (all)	0	2

Helicobacter gastritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Helicobacter infection		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Herpes simplex		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Herpes zoster		
subjects affected / exposed	2 / 54 (3.70%)	0 / 151 (0.00%)
occurrences (all)	2	0
Hordeolum		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Influenza		
subjects affected / exposed	1 / 54 (1.85%)	4 / 151 (2.65%)
occurrences (all)	1	6
Intestinal sepsis		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Joint abscess		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Laryngitis		
subjects affected / exposed	2 / 54 (3.70%)	0 / 151 (0.00%)
occurrences (all)	2	0
Localised infection		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Nasopharyngitis		
subjects affected / exposed	8 / 54 (14.81%)	21 / 151 (13.91%)
occurrences (all)	14	36

Oral herpes		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Otitis externa		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Otitis media		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Periodontitis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Pharyngitis		
subjects affected / exposed	2 / 54 (3.70%)	9 / 151 (5.96%)
occurrences (all)	3	9
Pharyngotonsillitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Pneumonia		
subjects affected / exposed	0 / 54 (0.00%)	4 / 151 (2.65%)
occurrences (all)	0	4
Pneumonia bacterial		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Pulmonary tuberculosis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Pulpitis dental		
subjects affected / exposed	1 / 54 (1.85%)	1 / 151 (0.66%)
occurrences (all)	1	1
Purulent discharge		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Pyelonephritis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1

Pyelonephritis acute		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Respiratory tract infection		
subjects affected / exposed	2 / 54 (3.70%)	2 / 151 (1.32%)
occurrences (all)	3	2
Respiratory tract infection viral		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	2	2
Rhinitis		
subjects affected / exposed	1 / 54 (1.85%)	13 / 151 (8.61%)
occurrences (all)	1	17
Septic shock		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Sinusitis		
subjects affected / exposed	2 / 54 (3.70%)	4 / 151 (2.65%)
occurrences (all)	2	4
Skin infection		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0
Suspected COVID-19		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Tonsillitis		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Tooth infection		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Tracheitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Tracheobronchitis		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	9 / 54 (16.67%) 14	13 / 151 (8.61%) 14	
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 54 (5.56%) 4	18 / 151 (11.92%) 24	
Vaginal infection subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Viral infection subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1	2 / 151 (1.32%) 4	
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Wound infection subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Metabolism and nutrition disorders			
Cholesterosis subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Copper deficiency subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	1 / 151 (0.66%) 1	
Dehydration subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 151 (0.00%) 0	
Diabetes mellitus			

subjects affected / exposed	2 / 54 (3.70%)	2 / 151 (1.32%)
occurrences (all)	2	2
Diabetes mellitus inadequate control		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	4
Dyslipidaemia		
subjects affected / exposed	0 / 54 (0.00%)	4 / 151 (2.65%)
occurrences (all)	0	4
Glucose tolerance impaired		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Hypercholesterolaemia		
subjects affected / exposed	1 / 54 (1.85%)	6 / 151 (3.97%)
occurrences (all)	1	6
Hyperglycaemia		
subjects affected / exposed	1 / 54 (1.85%)	2 / 151 (1.32%)
occurrences (all)	1	2
Hyperlipidaemia		
subjects affected / exposed	1 / 54 (1.85%)	3 / 151 (1.99%)
occurrences (all)	1	3
Hypertriglyceridaemia		
subjects affected / exposed	0 / 54 (0.00%)	4 / 151 (2.65%)
occurrences (all)	0	5
Hyperuricaemia		
subjects affected / exposed	0 / 54 (0.00%)	0 / 151 (0.00%)
occurrences (all)	0	0
Hypokalaemia		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Hypomagnesaemia		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Hyponatraemia		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Impaired fasting glucose		

subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Insulin resistance		
subjects affected / exposed	0 / 54 (0.00%)	1 / 151 (0.66%)
occurrences (all)	0	1
Obesity		
subjects affected / exposed	3 / 54 (5.56%)	3 / 151 (1.99%)
occurrences (all)	3	3
Type 2 diabetes mellitus		
subjects affected / exposed	1 / 54 (1.85%)	6 / 151 (3.97%)
occurrences (all)	1	6
Vitamin D deficiency		
subjects affected / exposed	1 / 54 (1.85%)	0 / 151 (0.00%)
occurrences (all)	1	0

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 July 2020	<p>The study design was updated to reflect that :</p> <ul style="list-style-type: none"><li>-subjects from only parent study of CLR_16_23 will be enrolled in the LTE</li><li>-The LTE will only assess safety as an objective</li></ul> <p>To reflect these changes, the following sections were updated: study assessments in text, table of assessments, study endpoints, objectives, background and rationale to reflect the change in study design and study methodology</p> <p>Additionally the following key changes were done:</p> <ul style="list-style-type: none"><li>-AESIs were added to list of safety variables</li><li>-Reference to independent DSMB and interim analysis were deleted based on recommendations by FDA guidelines</li><li>-Editorial changes including revision in table of contents, abbreviations</li><li>-Administrative changes</li></ul>

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported