



## Clinical trial results:

### A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo-Controlled Study to Evaluate the Long-Term Safety and the Efficacy of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip

#### Summary

EudraCT number	2015-003783-36
Trial protocol	BG DK SE DE LT GB PL ES HU RO IT
Global end of trial date	15 June 2021

#### Results information

Result version number	v1 (current)
This version publication date	01 July 2022
First version publication date	01 July 2022

#### Trial information

##### Trial identification

Sponsor protocol code	R475-PN-1523
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02683239
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Regeneron Pharmaceuticals, Inc.
Sponsor organisation address	777 Old Saw Mill River Road, Tarrytown, NY, United States, 10591
Public contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.com
Scientific contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.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	15 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 June 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the study was to describe the safety and tolerability of fasinumab, including adverse events of special interest (AESIs), in participants with pain due to radiographically-confirmed osteoarthritis (OA) of the knee or hip.

Protection of trial subjects:

It was the responsibility of both the sponsor and the investigator(s) to ensure that this clinical study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the ICH guidelines for GCP and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 February 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 761
Country: Number of subjects enrolled	Romania: 406
Country: Number of subjects enrolled	Spain: 90
Country: Number of subjects enrolled	Sweden: 42
Country: Number of subjects enrolled	United Kingdom: 653
Country: Number of subjects enrolled	Bulgaria: 202
Country: Number of subjects enrolled	Denmark: 135
Country: Number of subjects enrolled	Estonia: 26
Country: Number of subjects enrolled	Germany: 145
Country: Number of subjects enrolled	Hungary: 98
Country: Number of subjects enrolled	Lithuania: 40
Country: Number of subjects enrolled	Colombia: 123
Country: Number of subjects enrolled	Hong Kong: 57
Country: Number of subjects enrolled	Mexico: 127
Country: Number of subjects enrolled	Peru: 31
Country: Number of subjects enrolled	Chile: 163
Country: Number of subjects enrolled	South Africa: 547
Country: Number of subjects enrolled	Russian Federation: 170
Country: Number of subjects enrolled	Ukraine: 180

Country: Number of subjects enrolled	United States: 1335
Worldwide total number of subjects	5331
EEA total number of subjects	1945

Notes:

<b>Subjects enrolled per age group</b>	
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)	2695
From 65 to 84 years	2609
85 years and over	27

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total 13,945 participants were screened. Of those, 8614 were screen failures (14 - Adverse event; 587 - consent withdrawn; 7015 - did not meet criteria; 19 - investigator decision; 66 - lost to follow-up; 910 - Other; 3 - Serious Adverse Event) and 5331 met the eligibility criteria and were randomized to 1 of 7 treatment arms.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Carer, Assessor, Subject

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Fasinumab-matching Placebo Q4W/Q8W

Arm description:

Participants received fasinumab matching placebo SC injection, Q4W or Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Placebo
Investigational medicinal product name	Fasinumab-matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab-matching placebo into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 1 mg SC Q8W
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Arm description:

Participants received fasinumab 1 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 1 mg into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 1 mg SC Q4W
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Arm description:

Participants received fasinumab 1 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
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Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 1 mg into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 3 mg SC Q4W
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Arm description:

Participants received fasinumab 3 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 3 mg into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 6 mg SC Q8W
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Arm description:

Participants received fasinumab 6 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 6 mg the study drug into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 6 mg SC Q4W
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Arm description:

Participants received fasinumab 6 mg SC injection Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 6 mg the study drug into abdomen, thigh, or upper arm.

<b>Arm title</b>	Fasinumab 9 mg SC Q4W
------------------	-----------------------

Arm description:

Participants received fasinumab 9 mg SC injection, Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Arm type	Experimental
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Investigational medicinal product name	Fasinumab
Investigational medicinal product code	R475
Other name	REGN475
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of fasinumab 9 mg the study drug into abdomen, thigh, or upper arm.

Number of subjects in period 1	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W
Started	1260	971	975
Completed	800	738	756
Not completed	460	233	219
Physician decision	38	19	14
Consent withdrawn by subject	187	99	91
Adverse event, non-fatal	64	39	42
Protocol violation	35	23	26
Death	9	5	8
Unspecified	-	1	1
Lost to follow-up	77	24	25
Lack of efficacy	50	23	12

Number of subjects in period 1	Fasinumab 3 mg SC Q4W	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W
Started	214	1680	116
Completed	94	935	56
Not completed	120	745	60
Physician decision	73	143	14
Consent withdrawn by subject	18	248	22
Adverse event, non-fatal	16	189	9
Protocol violation	4	35	4
Death	-	12	1
Unspecified	-	1	-
Lost to follow-up	7	88	8
Lack of efficacy	2	29	2

Number of subjects in period 1	Fasinumab 9 mg SC Q4W
Started	115
Completed	44
Not completed	71
Physician decision	15
Consent withdrawn by subject	28

Adverse event, non-fatal	9
Protocol violation	5
Death	-
Unspecified	-
Lost to follow-up	11
Lack of efficacy	3

## Baseline characteristics

### Reporting groups

Reporting group title	Fasinumab-matching Placebo Q4W/Q8W
Reporting group description: Participants received fasinumab matching placebo SC injection, Q4W or Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 1 mg SC Q8W
Reporting group description: Participants received fasinumab 1 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 1 mg SC Q4W
Reporting group description: Participants received fasinumab 1 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 3 mg SC Q4W
Reporting group description: Participants received fasinumab 3 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 6 mg SC Q8W
Reporting group description: Participants received fasinumab 6 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 6 mg SC Q4W
Reporting group description: Participants received fasinumab 6 mg SC injection Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 9 mg SC Q4W
Reporting group description: Participants received fasinumab 9 mg SC injection, Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	

Reporting group values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W
Number of subjects	1260	971	975
Age categorical Units: Participants			
Age continuous Units: years arithmetic mean standard deviation	63.7 ± 9.24	65.0 ± 9.24	65.1 ± 8.57
Gender categorical Units: Participants			
Female	913	723	705
Male	347	248	270



Race			
Units: Subjects			
American Indian or Alaska Native	19	50	53
Asian	25	7	9
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	156	64	66
White	996	759	738
Unknown or Not Reported	63	91	109
Ethnicity			
Units: Subjects			
Hispanic or Latino	117	177	182
Not Hispanic or Latino	1139	791	787
Unknown or Not Reported	4	3	6
WOMAC Pain Subscale Score			
Units: Score on a Scale			
arithmetic mean	6.65	6.70	6.58
standard deviation	± 1.550	± 1.439	± 1.491
WOMAC Physical Function Subscale Score			
Units: Score on a Scale			
arithmetic mean	6.47	6.56	6.41
standard deviation	± 1.583	± 1.631	± 1.495
Patient Global Assessment Score of Osteoarthritis			
Units: Score on a Scale			
arithmetic mean	3.44	3.56	3.47
standard deviation	± 0.847	± 0.801	± 0.805

<b>Reporting group values</b>	Fasinumab 3 mg SC Q4W	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W
Number of subjects	214	1680	116
Age categorical			
Units: Participants			

Age continuous			
Units: years			
arithmetic mean	65.3	62.9	62.4
standard deviation	± 9.19	± 9.61	± 8.38
Gender categorical			
Units: Participants			
Female	149	1237	83
Male	65	443	33
Race			
Units: Subjects			
American Indian or Alaska Native	0	8	0
Asian	0	52	0
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	16	213	15
White	190	1352	99
Unknown or Not Reported	8	55	1
Ethnicity			

Units: Subjects			
Hispanic or Latino	6	124	8
Not Hispanic or Latino	207	1547	108
Unknown or Not Reported	1	9	0
WOMAC Pain Subscale Score			
Units: Score on a Scale			
arithmetic mean	6.48	6.58	99999
standard deviation	± 1.470	± 1.408	± 99999
WOMAC Physical Function Subscale Score			
Units: Score on a Scale			
arithmetic mean	6.27	6.38	99999
standard deviation	± 1.699	± 1.598	± 99999
Patient Global Assessment Score of Osteoarthritis			
Units: Score on a Scale			
arithmetic mean	3.42	3.42	99999
standard deviation	± 0.783	± 0.751	± 99999

<b>Reporting group values</b>	Fasinumab 9 mg SC Q4W	Total	
Number of subjects	115	5331	
Age categorical			
Units: Participants			

Age continuous			
Units: years			
arithmetic mean	63.4		
standard deviation	± 9.89	-	
Gender categorical			
Units: Participants			
Female	76	3886	
Male	39	1445	
Race			
Units: Subjects			
American Indian or Alaska Native	1	131	
Asian	0	93	
Native Hawaiian or Other Pacific Islander	0	2	
Black or African American	12	542	
White	102	4236	
Unknown or Not Reported	0	327	
Ethnicity			
Units: Subjects			
Hispanic or Latino	8	622	
Not Hispanic or Latino	107	4686	
Unknown or Not Reported	0	23	
WOMAC Pain Subscale Score			
Units: Score on a Scale			
arithmetic mean	99999		
standard deviation	± 99999	-	
WOMAC Physical Function Subscale Score			

Units: Score on a Scale			
arithmetic mean	99999		
standard deviation	± 99999	-	
Patient Global Assessment Score of Osteoarthritis			
Units: Score on a Scale			
arithmetic mean	99999		
standard deviation	± 99999	-	

## End points

### End points reporting groups

Reporting group title	Fasinumab-matching Placebo Q4W/Q8W
Reporting group description: Participants received fasinumab matching placebo SC injection, Q4W or Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 1 mg SC Q8W
Reporting group description: Participants received fasinumab 1 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 1 mg SC Q4W
Reporting group description: Participants received fasinumab 1 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 3 mg SC Q4W
Reporting group description: Participants received fasinumab 3 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 6 mg SC Q8W
Reporting group description: Participants received fasinumab 6 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 6 mg SC Q4W
Reporting group description: Participants received fasinumab 6 mg SC injection Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	
Reporting group title	Fasinumab 9 mg SC Q4W
Reporting group description: Participants received fasinumab 9 mg SC injection, Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.	

### Primary: Number of Participants With Adverse Events (AEs) During Treatment Period

End point title	Number of Participants With Adverse Events (AEs) During Treatment Period <sup>[1]</sup>
End point description: An AE was any untoward medical occurrence in a subject administered a study drug which may or may not have a causal relationship with the study drug. Therefore, an AE was any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease which was temporally associated with the use of a study drug, whether or not considered related to the study drug. Number of participants with AEs during treatment period were reported. The safety analysis set for the evaluation of long-term safety (SAF-LTS) included all randomized participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated).	
End point type	Primary
End point timeframe: Baseline up to 52 weeks	

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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	1055	840	885	185

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	1487	93	92	

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants With AEs up to 72 Weeks

End point title	Number of Participants With AEs up to 72 Weeks <sup>[2]</sup>
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End point description:

An AE was any untoward medical occurrence in a participant administered a study drug which may or may not have a causal relationship with the study drug. Therefore, an AE was any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease which was temporally associated with the use of a study drug, whether or not considered related to the study drug. Number of participants with AEs up to 72 weeks were reported. The SAF-LTS included all randomised participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated).

End point type	Primary
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End point timeframe:

Baseline up to 72 weeks

Notes:

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

Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	1112	867	902	192

End point values	Fasimumab 6 mg SC Q8W	Fasimumab 6 mg SC Q4W	Fasimumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	1570	106	106	

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants With Serious AEs During Treatment Period

End point title	Number of Participants With Serious AEs During Treatment Period <sup>[3]</sup>
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End point description:

An serious AEs was any untoward medical occurrence that: Resulted in death; was life-threatening; required in-patient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of one's ability to conduct normal life functions); was a congenital anomaly/birth defect; was an important medical event: Important medical events may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the subject or may require intervention to prevent 1 of the other serious outcomes listed above. Number of subjects with serious AEs during treatment period were reported. The SAF-LTS included all randomised subjects in the overall study who received any study drug; it was based on the treatment-as-received (as treated).

End point type	Primary
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End point timeframe:

Baseline up to 52 weeks

Notes:

[3] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasimumab-matching Placebo Q4W/Q8W	Fasimumab 1 mg SC Q8W	Fasimumab 1 mg SC Q4W	Fasimumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	82	57	70	13

End point values	Fasimumab 6 mg SC Q8W	Fasimumab 6 mg SC Q4W	Fasimumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	107	5	3	

## Statistical analyses

No statistical analyses for this end point

**Primary: Number of Participants With Serious AEs up to 72 Weeks**

End point title	Number of Participants With Serious AEs up to 72 Weeks <sup>[4]</sup>
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End point description:

An serious AEs was any untoward medical occurrence that: Resulted in death; was life-threatening; required in-patient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of one's ability to conduct normal life functions); was a congenital anomaly/birth defect; was an important medical event: Important medical events may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the participant or may require intervention to prevent 1 of the other serious outcomes listed above. Number of participants with serious AEs up to 72 weeks were reported. The SAF-LTS included all randomised participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated).

End point type	Primary
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End point timeframe:

Baseline up to 72 weeks

Notes:

[4] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	173	138	176	44

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	413	28	26	

**Statistical analyses**

No statistical analyses for this end point

**Primary: Number of Participants With Adverse Events of Special Interests (AESIs) During Treatment Period**

End point title	Number of Participants With Adverse Events of Special Interests (AESIs) During Treatment Period <sup>[5]</sup>
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End point description:

AESIs were followings: Adjudicated arthropathy (as confirmed by adjudication); Sympathetic nervous system dysfunction (as diagnosed after consultation with an appropriate specialist, such as a neurologist and/or cardiologist); Peripheral sensory AEs that required a neurology or other specialty consultation; Joint replacement (JR) surgery. Number of participants with AESIs during treatment period were reported. The SAF-LTS included all randomised subjects in the overall study who received any study drug; it was based on the treatment-as-received (as treated).

End point type	Primary
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End point timeframe:

Baseline up to 52 weeks

Notes:

[5] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	28	63	63	20

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	64	2	0	

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants With AESIs up to 72 Weeks

End point title	Number of Participants With AESIs up to 72 Weeks <sup>[6]</sup>
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End point description:

AESIs were followings: Adjudicated arthropathy (as confirmed by adjudication); Sympathetic nervous system dysfunction (as diagnosed after consultation with an appropriate specialist, such as a neurologist and/or cardiologist); Peripheral sensory AEs that required a neurology or other specialty consultation; Joint replacement (JR) surgery. Number of participants with AESIs up to 72 weeks were reported. The SAF-LTS included all randomised participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated).

End point type	Primary
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End point timeframe:

Baseline up to 72 weeks

Notes:

[6] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants	80	150	159	41



End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants	382	22	14	

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants With Potentially Clinically Significant Abnormal Laboratory Values During Treatment Period

End point title	Number of Participants With Potentially Clinically Significant Abnormal Laboratory Values During Treatment Period <sup>[7]</sup>
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End point description:

Number of participants with potentially clinically significant abnormal values in following laboratory parameters hematology, chemistry and urinalysis during treatment period were reported. Clinical significance was determined by the investigator. The SAF-LTS included all randomized participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated). Here 'n' = number of evaluable participants at the specified timeframe.

End point type	Primary
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End point timeframe:

Baseline up to 52 weeks

Notes:

[7] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants				
Hematology (n=1016, 854, 875, 176, 1405, 88, 85)	195	236	241	28
Chemistry (n=1181, 941, 950, 207, 1627, 111, 108)	403	365	403	105
Urinalysis (n=1131, 940, 949, 207, 1588, 58, 55)	32	42	45	2

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants				
Hematology (n=1016, 854, 875, 176, 1405, 88, 85)	304	7	11	
Chemistry (n=1181, 941, 950, 207, 1627, 111, 108)	717	36	34	

Urinalysis (n=1131, 940, 949, 207, 1588, 58, 55)	55	1	1	
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## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Potentially Clinically Significant Abnormal Laboratory Values up to 72 Weeks

End point title	Number of Participants With Potentially Clinically Significant Abnormal Laboratory Values up to 72 Weeks <sup>[8]</sup>
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End point description:

Number of participants with potentially clinically significant abnormal values in following laboratory parameters hematology, chemistry and urinalysis up to 72 weeks were reported. Clinical significance was determined by the investigator. The SAF-LTS included all randomized participants in the overall study who received any study drug; it was based on the treatment-as-received (as treated). Here 'n' = number of evaluable participants at the specified timeframe.

End point type	Primary
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End point timeframe:

End of treatment up to 72 weeks

Notes:

[8] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1257	966	974	214
Units: Participants				
Hematology (n=1007, 808, 814, 190, 1426,104, 100)	171	149	154	23
Chemistry (n=1032, 813, 818, 195, 1459, 107, 100)	267	228	225	59
Urinalysis (n=1015, 811, 814, 190, 1442, 103, 99)	16	24	18	1

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1677	116	115	
Units: Participants				
Hematology (n=1007, 808, 814, 190, 1426,104, 100)	279	29	32	
Chemistry (n=1032, 813, 818, 195, 1459, 107, 100)	474	36	40	
Urinalysis (n=1015, 811, 814, 190, 1442, 103, 99)	37	5	3	

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Anti-drug Antibody (ADA) During Treatment Period

End point title	Number of Participants With Anti-drug Antibody (ADA) During Treatment Period <sup>[9]</sup> <sup>[10]</sup>
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End point description:

Immunogenicity was characterized by ADA responses & titers. Responses categories: Negative - ADA negative response at all time points, regardless of missing samples; Pre-existing immunoreactivity - ADA positive response at baseline with all post first dose negative results or positive response at baseline with all post first dose ADA responses less than (<) 9-fold over baseline titer levels; Treatment-boosted response - positive response in the assay post first dose, greater than or equal to (≥) 9-fold over baseline titer levels, when baseline results are positive; Treatment-emergent response - ADA positive response in the fasinumab ADA assay post first dose when baseline results = negative or missing. The ADA analysis set for the long-term safety population included all participants who received any study drug (SAF-LTS) and had at least 1 non-missing ADA result following the first dose of study drug. Here 'n' = number of evaluable participants during the efficacy sub-study.

End point type	Primary
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End point timeframe:

Baseline to 16 weeks

Notes:

[9] - 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: Only descriptive data was planned to be analyzed for this endpoint.

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

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	205	200	210	208
Units: Participants				
ADA Negative Status	197	193	200	200
Pre-existing Immunoreactivity	5	3	7	6
Treatment-Emergent Response	3	4	3	2
Treatment-Boosted Response	0	0	0	0

End point values	Fasinumab 6 mg SC Q8W			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: Participants				

ADA Negative Status	200			
Pre-existing Immunoreactivity	5			
Treatment-Emergent Response	4			
Treatment-Boosted Response	0			

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With ADA up to 72 Weeks

End point title	Number of Participants With ADA up to 72 Weeks <sup>[11]</sup>
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End point description:

Immunogenicity was characterized by ADA responses & titers. Responses categories: Negative - ADA negative response at all time points, regardless of missing samples; Pre-existing immunoreactivity - ADA positive response at baseline with all post first dose negative results or positive response at baseline with all post first dose ADA responses < 9-fold over baseline titer levels; Treatment-boosted response - positive response in the assay post first dose, ≥9-fold over baseline titer levels, when baseline results are positive; Treatment-emergent response - ADA positive response in the fasinumab ADA assay post first dose when baseline results = negative or missing. The ADA analysis set for the long-term safety population included all participants who received any study drug (SAF-LTS) and had at least 1 non-missing ADA result following the first dose of study drug. Here 'n' = number of evaluable participants during the specified time frame.

End point type	Primary
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End point timeframe:

Baseline up to 72 weeks

Notes:

[11] - 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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1153	911	929	208
Units: Participants				
ADA Negative Status	1115	885	907	200
Pre-existing Immunoreactivity	22	16	12	6
Treatment-Emergent Response	16	10	10	2
Treatment-Boosted Response	0	0	0	0

End point values	Fasinumab 6 mg SC Q8W	Fasinumab 6 mg SC Q4W	Fasinumab 9 mg SC Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1603	111	105	
Units: Participants				
ADA Negative Status	1547	108	104	
Pre-existing Immunoreactivity	37	2	1	
Treatment-Emergent Response	19	1	0	
Treatment-Boosted Response	0	0	0	

## Statistical analyses

No statistical analyses for this end point

### Primary: Change from Baseline to Week 16 in the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Pain Subscale Score

End point title	Change from Baseline to Week 16 in the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Pain Subscale Score <sup>[12]</sup>
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End point description:

Here 'n' = number of evaluable participants at the specified time points

End point type	Primary
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End point timeframe:

Baseline to Week 16

Notes:

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

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	214	215	212	213
Units: Score on a Scale				
least squares mean (standard error)	-1.55 ( $\pm$ 0.178)	-2.28 ( $\pm$ 0.175)	-2.77 ( $\pm$ 0.171)	-2.78 ( $\pm$ 0.174)

End point values	Fasinumab 6 mg SC Q8W			
Subject group type	Reporting group			
Number of subjects analysed	213			
Units: Score on a Scale				
least squares mean (standard error)	-2.59 ( $\pm$ 0.174)			

## Statistical analyses

Statistical analysis title	Placebo vs Fasinumab 1 mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q8W

Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.159
upper limit	-0.293
Variability estimate	Standard error of the mean
Dispersion value	0.221

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 1 mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q4W
Number of subjects included in analysis	426
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.646
upper limit	-0.793
Variability estimate	Standard error of the mean
Dispersion value	0.217

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 3 mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 3 mg SC Q4W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.664
upper limit	-0.793
Variability estimate	Standard error of the mean
Dispersion value	0.222

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 6 mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 6 mg SC Q8W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.477
upper limit	-0.606
Variability estimate	Standard error of the mean
Dispersion value	0.222

### Primary: Change from Baseline to Week 16 in WOMAC Physical Function Subscale Score

End point title	Change from Baseline to Week 16 in WOMAC Physical Function Subscale Score <sup>[13]</sup>
End point description: Here 'n' = number of evaluable participants at the specified time point	
End point type	Primary
End point timeframe: Baseline to Week 16	

Notes:

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

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	207	212	212	208
Units: Score on a Scale				
least squares mean (standard error)	-1.35 (±	-2.09 (±	-2.55 (±	-2.61 (±

0.177)

0.175)

0.173)

0.177)

<b>End point values</b>	Fasinumab 6 mg SC Q8W			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: Score on a Scale				
least squares mean (standard error)	-2.48 ( $\pm$ 0.177)			

## Statistical analyses

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 1 mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q8W
Number of subjects included in analysis	419
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0007
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.163
upper limit	-0.309
Variability estimate	Standard error of the mean
Dispersion value	0.218

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 1 mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q4W
Number of subjects included in analysis	419
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.624
upper limit	-0.768



Variability estimate	Standard error of the mean
Dispersion value	0.218

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 3mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 3 mg SC Q4W
Number of subjects included in analysis	415
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.698
upper limit	-0.822
Variability estimate	Standard error of the mean
Dispersion value	0.223

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 6 mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 6 mg SC Q8W
Number of subjects included in analysis	416
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.564
upper limit	-0.695
Variability estimate	Standard error of the mean
Dispersion value	0.222

## Secondary: Change from Baseline to Week 16 in Patient Global Assessment (PGA) Score of Osteoarthritis

End point title	Change from Baseline to Week 16 in Patient Global Assessment (PGA) Score of Osteoarthritis <sup>[14]</sup>
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End point description:

Here 'n' = number of evaluable participants at the specified time point

End point type	Secondary
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End point timeframe:

Baseline to Week 16

Notes:

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

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	214	214	217	213
Units: Score on a Scale				
least squares mean (standard error)	-0.66 ( $\pm$ 0.070)	-0.87 ( $\pm$ 0.071)	-0.93 ( $\pm$ 0.069)	-0.99 ( $\pm$ 0.071)

End point values	Fasinumab 6 mg SC Q8W			
Subject group type	Reporting group			
Number of subjects analysed	214			
Units: Score on a Scale				
least squares mean (standard error)	-0.96 ( $\pm$ 0.072)			

## Statistical analyses

Statistical analysis title	Placebo vs. Fasinumab 1mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q8W
Number of subjects included in analysis	428
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	-0.028
Variability estimate	Standard error of the mean
Dispersion value	0.09

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 1 mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 1 mg SC Q4W
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0025
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.437
upper limit	-0.093
Variability estimate	Standard error of the mean
Dispersion value	0.088

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 3 mg SC Q4W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 3 mg SC Q4W
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.496
upper limit	-0.145
Variability estimate	Standard error of the mean
Dispersion value	0.09

<b>Statistical analysis title</b>	Placebo vs. Fasinumab 6 mg SC Q8W
Comparison groups	Fasinumab-matching Placebo Q4W/Q8W v Fasinumab 6 mg SC Q8W
Number of subjects included in analysis	428
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Least Squares Mean
Point estimate	-0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.466
upper limit	-0.118
Variability estimate	Standard error of the mean
Dispersion value	0.089

## Secondary: Percentage Response from Baseline at Week 16 in the WOMAC Pain Subscale Score

End point title	Percentage Response from Baseline at Week 16 in the WOMAC Pain Subscale Score <sup>[15]</sup>
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End point description:

Participants who achieved a response, where response was defined as an improvement by  $\geq 30\%$  in WOMAC pain subscale score; Here 'n' = number of evaluable participants at the specified time point

End point type	Secondary
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End point timeframe:

Week 16

Notes:

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

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Fasinumab-matching Placebo Q4W/Q8W	Fasinumab 1 mg SC Q8W	Fasinumab 1 mg SC Q4W	Fasinumab 3 mg SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	214	215	217	214
Units: Percentage of Participants				
number (not applicable)				
$\geq 30\%$ reduction from baseline to week 16	35.5	50.2	58.1	55.1

End point values	Fasinumab 6 mg SC Q8W			
Subject group type	Reporting group			
Number of subjects analysed	214			
Units: Percentage of Participants				
number (not applicable)				
$\geq 30\%$ reduction from baseline to week 16	53.3			

## Statistical analyses



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From first dose to end of follow-up period (Week 72)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received fasinumab matching placebo SC injection, Q4W or Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 1mg SC Q8W
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Reporting group description:

Participants received fasinumab 1 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 1mg SC Q4W
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Reporting group description:

Participants received fasinumab 1 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 3mg SC Q4W
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Reporting group description:

Participants received fasinumab 3 mg SC injection, Q4W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 6mg SC Q8W
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Reporting group description:

Participants received fasinumab 6 mg SC injection, Q8W from Day 1 up to 52 weeks. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 6mg SC Q4W
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Reporting group description:

Participants received fasinumab 6 mg SC injection Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Reporting group title	Fasinumab 9mg SC Q4W
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Reporting group description:

Participants received fasinumab 9 mg SC injection, Q4W from Day 1 up to 37 weeks of 52-week treatment period. Participants were permitted to use only acetaminophen/paracetamol as rescue medication. The treatment period included both study visits and a phone contact at 52 weeks.

Serious adverse events	Placebo	Fasinumab 1mg SC Q8W	Fasinumab 1mg SC Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	173 / 1257 (13.76%)	138 / 966 (14.29%)	176 / 974 (18.07%)
number of deaths (all causes)	7	3	6

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Basal cell carcinoma			
subjects affected / exposed	2 / 1257 (0.16%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Benign renal neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Breast cancer			
subjects affected / exposed	2 / 1257 (0.16%)	3 / 966 (0.31%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Breast cancer stage II			

subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Malignant melanoma in situ			



subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer stage I			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Ovarian neoplasm			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage III			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland neoplasm			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Tonsil cancer			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Acoustic neuroma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma of colon			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Bladder cancer			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholesteatoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myelomonocytic leukaemia			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of liver			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Inflammatory carcinoma of breast stage III			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal neoplasm			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Metastases to liver			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Non-Hodgkin's lymphoma			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal neoplasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Thymoma			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour necrosis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	5 / 1257 (0.40%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Hypotension			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Venous thrombosis			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Aortic dilatation			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Giant cell arteritis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Varicose vein			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
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>			
Hip arthroplasty			
subjects affected / exposed	9 / 1257 (0.72%)	7 / 966 (0.72%)	7 / 974 (0.72%)
occurrences causally related to treatment / all	0 / 9	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	13 / 1257 (1.03%)	13 / 966 (1.35%)	11 / 974 (1.13%)
occurrences causally related to treatment / all	0 / 14	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee operation			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Cataract operation			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint arthroplasty			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>General disorders and administration site conditions</b>			
Chest pain			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	3 / 1257 (0.24%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 1



Peripheral swelling			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Sarcoidosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 1257 (0.16%)	2 / 966 (0.21%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Breast mass			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital haemorrhage			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Uterine adhesions			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Endometrial thickening			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Rectocele			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 1257 (0.24%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottic cyst			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Rhinorrhoea			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Acute respiratory failure			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum disorder			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mood disorder due to a general medical condition			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device loosening			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Device dislocation			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transaminases increased			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Liver function test abnormal			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Diagnostic procedure			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Fall			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Forearm fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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

Fracture displacement			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Humerus fracture			
subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	3 / 1257 (0.24%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Meniscus injury			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Multiple injuries			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Muscle rupture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Muscle strain			



subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Pneumothorax traumatic			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress fracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Tendon dislocation			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Upper limb fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Concussion			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Gun shot wound			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Radius fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Joint injury			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Post procedural constipation			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pulmonary embolism			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	2 / 1257 (0.16%)	2 / 966 (0.21%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 1257 (0.24%)	1 / 966 (0.10%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 chronic			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	2 / 1257 (0.16%)	3 / 966 (0.31%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Myocardial infarction			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 1257 (0.08%)	3 / 966 (0.31%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Atrial flutter			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Acute coronary syndrome			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Bundle branch block right			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 acute			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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			
Auditory nerve disorder			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	2 / 1257 (0.16%)	2 / 966 (0.21%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fistula			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Cerebrovascular accident			



subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial spasm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 radiculopathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Paraesthesia			

subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	4 / 974 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Vertebral artery stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Axonal neuropathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral radiculopathy			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgic amyotrophy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless legs syndrome			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 1257 (0.32%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Vestibular ataxia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Vertigo positional			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Cataract			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular hole			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open angle glaucoma			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Retinal detachment			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Borderline glaucoma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maculopathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Abdominal pain upper			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Abdominal wall haematoma			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Chronic gastritis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Diaphragmatic hernia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Diverticulum intestinal			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Haemorrhoids			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial eventration			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Ileus paralytic			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Inguinal hernia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			



subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Terminal ileitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Intestinal obstruction			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Volvulus			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Abdominal discomfort			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Constipation			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal hernia			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Pancreatitis acute			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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			
Autoimmune hepatitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Bile duct stone			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Lichen planus			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Idiopathic angioedema			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin haemorrhage			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
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 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bladder stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Calculus urinary			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Nephrolithiasis			
subjects affected / exposed	2 / 1257 (0.16%)	3 / 966 (0.31%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder prolapse			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	16 / 1257 (1.27%)	15 / 966 (1.55%)	20 / 974 (2.05%)
occurrences causally related to treatment / all	0 / 17	0 / 17	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bursitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb mass			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	9 / 1257 (0.72%)	7 / 966 (0.72%)	17 / 974 (1.75%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rapidly progressive osteoarthritis			
subjects affected / exposed	8 / 1257 (0.64%)	23 / 966 (2.38%)	27 / 974 (2.77%)
occurrences causally related to treatment / all	0 / 9	0 / 23	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subchondral insufficiency fracture			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon disorder			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon pain			



subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Ankylosing spondylitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint range of motion decreased			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint stiffness			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Knee deformity			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metatarsalgia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck mass			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyositis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Spondylolisthesis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	3 / 974 (0.31%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 1257 (0.08%)	3 / 966 (0.31%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Mastitis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	4 / 1257 (0.32%)	1 / 966 (0.10%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Sepsis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Wound infection			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 1257 (0.00%)	4 / 966 (0.41%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 1257 (0.08%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 1257 (0.00%)	1 / 966 (0.10%)	0 / 974 (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
Abscess intestinal			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Appendicitis perforated			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Arthritis bacterial			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Bronchitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	2 / 974 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Device related infection			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Hepatitis C			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			



subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Diabetic ketoacidosis			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Hyponatraemia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Metabolic syndrome			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (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
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1257 (0.00%)	0 / 966 (0.00%)	1 / 974 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	2 / 1257 (0.16%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 1257 (0.08%)	0 / 966 (0.00%)	0 / 974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Fasinumab 3mg SC Q4W	Fasinumab 6mg SC Q8W	Fasinumab 6mg SC Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	44 / 214 (20.56%)	413 / 1677 (24.63%)	28 / 116 (24.14%)
number of deaths (all causes)	0	9	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign renal neoplasm			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Brain neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage II			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Colon cancer			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 adenocarcinoma			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Hepatic neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer stage I			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage III			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Transitional cell cancer of the renal pelvis and ureter			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 leiomyoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acoustic neuroma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Bone neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Brain neoplasm malignant			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cholesteatoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of liver			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory carcinoma of breast stage III			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Papillary thyroid cancer			



subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal neoplasm			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thymoma			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Tumour necrosis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Hypertensive crisis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Hypertensive urgency			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Peripheral venous disease			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dilatation			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Lymphoedema			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	4 / 214 (1.87%)	28 / 1677 (1.67%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 4	0 / 30	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee operation			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Joint arthroplasty			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Peripheral swelling			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Asthenia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
<b>Immune system disorders</b>			
Hypersensitivity			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Reproductive system and breast disorders</b>			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast mass			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cystocele			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Genital haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ovarian cyst			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 adhesions			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 prolapse			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial thickening			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Uterine polyp			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Asthma			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottic cyst			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Epistaxis			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinorrhoea			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Emphysema			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Nasal septum disorder			



subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Pneumothorax			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Psychotic disorder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device loosening			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diagnostic procedure			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 214 (0.00%)	4 / 1677 (0.24%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Joint dislocation			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 214 (0.00%)	5 / 1677 (0.30%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Stress fracture			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon dislocation			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 214 (0.00%)	4 / 1677 (0.24%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Wrist fracture			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Cervical vertebral fracture			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Contusion			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Foot fracture			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Joint injury			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Patella fracture			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Periprosthetic fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural constipation			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pulmonary embolism			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Postoperative wound complication			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Procedural pain			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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	1 / 214 (0.47%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			



subjects affected / exposed	0 / 214 (0.00%)	4 / 1677 (0.24%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Arrhythmia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 214 (1.40%)	5 / 1677 (0.30%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Bradycardia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Sinus node dysfunction			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block right			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Mitral valve incompetence			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Auditory nerve disorder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 214 (0.00%)	5 / 1677 (0.30%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cerebrospinal fistula			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dizziness			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial spasm			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Lumbar radiculopathy			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Neuropathy peripheral			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 214 (0.47%)	1 / 1677 (0.06%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Vertebral artery stenosis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Carotid artery occlusion			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Myasthenia gravis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Neuralgic amyotrophy			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Restless legs syndrome			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytosis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Vestibular ataxia			



subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Vestibular disorder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Macular hole			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Open angle glaucoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borderline glaucoma			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Maculopathy			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Visual impairment			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Colitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial eventration			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Ileus paralytic			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Mechanical ileus			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Terminal ileitis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Intestinal obstruction			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal discomfort			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Gastric ulcer			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Gastrointestinal perforation			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Internal hernia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Peptic ulcer			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cholelithiasis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Dermatitis allergic			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic angioedema			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin haemorrhage			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Bladder stenosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Calculus bladder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			



subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Urinary incontinence			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Bladder prolapse			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 failure			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Stress urinary incontinence			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Urethral stenosis			

subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 214 (2.34%)	47 / 1677 (2.80%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 5	0 / 51	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Back pain			
subjects affected / exposed	1 / 214 (0.47%)	4 / 1677 (0.24%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc degeneration subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Joint swelling subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb mass subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 / 214 (0.00%)	5 / 1677 (0.30%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness subjects affected / exposed	2 / 214 (0.93%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis subjects affected / exposed	5 / 214 (2.34%)	41 / 1677 (2.44%)	4 / 116 (3.45%)
occurrences causally related to treatment / all	0 / 5	0 / 42	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rapidly progressive osteoarthritis			

subjects affected / exposed	10 / 214 (4.67%)	157 / 1677 (9.36%)	8 / 116 (6.90%)
occurrences causally related to treatment / all	0 / 11	0 / 199	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 214 (0.00%)	9 / 1677 (0.54%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subchondral insufficiency fracture			
subjects affected / exposed	0 / 214 (0.00%)	21 / 1677 (1.25%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 21	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon disorder			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon pain			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankylosing spondylitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			

subjects affected / exposed	0 / 214 (0.00%)	3 / 1677 (0.18%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Joint range of motion decreased			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Joint stiffness			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee deformity			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metatarsalgia			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Neck mass			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Neck pain			

subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Osteitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Polymyositis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	1 / 214 (0.47%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			

subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Tenosynovitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 214 (0.00%)	6 / 1677 (0.36%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Cystitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Mastitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Peritonitis			
subjects affected / exposed	1 / 214 (0.47%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 214 (0.47%)	7 / 1677 (0.42%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			



subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Sepsis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Septic shock			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 214 (0.47%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Abscess limb			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Bronchitis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Endocarditis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Endocarditis bacterial			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Orchitis			
subjects affected / exposed	1 / 214 (0.47%)	0 / 1677 (0.00%)	0 / 116 (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
Otitis externa			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Vestibular neuronitis			

subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Hyponatraemia			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
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 syndrome			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 214 (0.00%)	1 / 1677 (0.06%)	0 / 116 (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
Dehydration			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 214 (0.00%)	0 / 1677 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 214 (0.00%)	2 / 1677 (0.12%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Fasinumab 9mg SC Q4W		
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 115 (22.61%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of bladder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign renal neoplasm			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Breast cancer				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer stage II				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clear cell renal cell carcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder adenocarcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningioma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine tumour				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer stage I				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage III				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal neoplasm				



subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Salivary gland neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsil cancer				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell cancer of the renal pelvis and ureter				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acoustic neuroma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma of colon				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma pancreas				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder cancer				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm malignant				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholesteatoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic lymphocytic leukaemia				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic myelomonocytic leukaemia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon adenoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial adenocarcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma of liver				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inflammatory carcinoma of breast stage III				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung cancer metastatic				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal neoplasm				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superficial spreading melanoma stage unspecified				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thymoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour necrosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive urgency			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis limb				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic dilatation				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Giant cell arteritis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoedema				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral vascular disorder				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Knee arthroplasty			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Knee operation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract operation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint arthroplasty			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Death			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoidosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast			



disorders				
Benign prostatic hyperplasia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast mass				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystocele				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital haemorrhage				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine adhesions				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal prolapse				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial thickening				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectocele			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine polyp			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiectasis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epiglottic cyst			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epistaxis			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vocal cord polyp			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinorrhoea			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Emphysema			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum disorder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device loosening			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diagnostic procedure				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Ankle fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Forearm fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fracture displacement				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meniscus injury				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple injuries				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle rupture				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle strain			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue injury			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			



subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon dislocation				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gun shot wound				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alcohol poisoning				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foot fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligament sprain			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patella fracture			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periprosthetic fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural constipation				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural pulmonary embolism				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound complication				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon injury				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute coronary syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bundle branch block right			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Auditory nerve disorder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	2 / 115 (1.74%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cauda equina syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fistula			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial spasm			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lacunar infarction			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathy peripheral			



subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiculopathy				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular encephalopathy				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertebrobasilar insufficiency				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral artery stenosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Axonal neuropathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical radiculopathy			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intracranial aneurysm			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myasthenia gravis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuralgic amyotrophy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Restless legs syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypochromic anaemia			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytosis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular ataxia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular disorder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macular hole			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Open angle glaucoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Borderline glaucoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Maculopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Visual impairment			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hernial eventration				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incarcerated inguinal hernia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mechanical ileus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal stenosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Terminal ileitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			



subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Volvulus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal discomfort			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecaloma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal perforation			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Internal hernia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis chronic			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lichen planus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Idiopathic angioedema			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin haemorrhage			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder stenosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus bladder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder prolapse			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress urinary incontinence			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 115 (1.74%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arthritis reactive			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Back pain				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dupuytren's contracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc degeneration				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint swelling				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb mass				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteochondrosis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rapidly progressive osteoarthritis				
subjects affected / exposed	6 / 115 (5.22%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subchondral insufficiency fracture				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Synovitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon disorder				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon pain			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankylosing spondylitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthropathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint range of motion decreased			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint stiffness			



subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Knee deformity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metatarsalgia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck mass				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteitis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polymyositis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				

subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis staphylococcal			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess intestinal				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis perforated				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis bacterial				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis adenovirus				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of bronchiectasis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orchitis				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural cellulitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic syndrome			



subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gout			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	Placebo	Fasinumab 1mg SC Q8W	Fasinumab 1mg SC Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	984 / 1257 (78.28%)	792 / 966 (81.99%)	816 / 974 (83.78%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	53 / 1257 (4.22%)	48 / 966 (4.97%)	56 / 974 (5.75%)
occurrences (all)	60	53	62
Contusion			
subjects affected / exposed	34 / 1257 (2.70%)	35 / 966 (3.62%)	36 / 974 (3.70%)
occurrences (all)	42	48	48
Vascular disorders			

Hypertension subjects affected / exposed occurrences (all)	53 / 1257 (4.22%) 55	54 / 966 (5.59%) 59	46 / 974 (4.72%) 50
Nervous system disorders Headache subjects affected / exposed occurrences (all)	395 / 1257 (31.42%) 1445	370 / 966 (38.30%) 948	417 / 974 (42.81%) 1080
Paraesthesia subjects affected / exposed occurrences (all)	41 / 1257 (3.26%) 53	54 / 966 (5.59%) 66	75 / 974 (7.70%) 94
Hypoaesthesia subjects affected / exposed occurrences (all)	34 / 1257 (2.70%) 42	25 / 966 (2.59%) 32	27 / 974 (2.77%) 31
Carpal tunnel syndrome subjects affected / exposed occurrences (all)	27 / 1257 (2.15%) 30	42 / 966 (4.35%) 49	49 / 974 (5.03%) 58
Dizziness subjects affected / exposed occurrences (all)	61 / 1257 (4.85%) 74	45 / 966 (4.66%) 49	48 / 974 (4.93%) 61
Sciatica subjects affected / exposed occurrences (all)	24 / 1257 (1.91%) 30	27 / 966 (2.80%) 31	33 / 974 (3.39%) 34
General disorders and administration site conditions Peripheral swelling subjects affected / exposed occurrences (all)	16 / 1257 (1.27%) 20	11 / 966 (1.14%) 11	20 / 974 (2.05%) 23
Oedema peripheral subjects affected / exposed occurrences (all)	32 / 1257 (2.55%) 38	26 / 966 (2.69%) 29	24 / 974 (2.46%) 25
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	110 / 1257 (8.75%) 159	91 / 966 (9.42%) 148	117 / 974 (12.01%) 175
Diarrhoea subjects affected / exposed occurrences (all)	58 / 1257 (4.61%) 67	55 / 966 (5.69%) 67	46 / 974 (4.72%) 61

Nausea subjects affected / exposed occurrences (all)	37 / 1257 (2.94%) 41	26 / 966 (2.69%) 27	22 / 974 (2.26%) 24
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	409 / 1257 (32.54%) 759	347 / 966 (35.92%) 633	349 / 974 (35.83%) 627
Back pain subjects affected / exposed occurrences (all)	203 / 1257 (16.15%) 362	206 / 966 (21.33%) 335	184 / 974 (18.89%) 299
Pain in extremity subjects affected / exposed occurrences (all)	111 / 1257 (8.83%) 149	114 / 966 (11.80%) 144	123 / 974 (12.63%) 180
Myalgia subjects affected / exposed occurrences (all)	77 / 1257 (6.13%) 100	60 / 966 (6.21%) 81	56 / 974 (5.75%) 75
Osteoarthritis subjects affected / exposed occurrences (all)	74 / 1257 (5.89%) 101	56 / 966 (5.80%) 82	73 / 974 (7.49%) 98
Joint swelling subjects affected / exposed occurrences (all)	36 / 1257 (2.86%) 42	31 / 966 (3.21%) 32	35 / 974 (3.59%) 38
Rapidly progressive osteoarthritis subjects affected / exposed occurrences (all)	22 / 1257 (1.75%) 23	47 / 966 (4.87%) 50	60 / 974 (6.16%) 62
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	183 / 1257 (14.56%) 231	189 / 966 (19.57%) 289	210 / 974 (21.56%) 303
Upper respiratory tract infection subjects affected / exposed occurrences (all)	142 / 1257 (11.30%) 198	82 / 966 (8.49%) 103	89 / 974 (9.14%) 113
Urinary tract infection subjects affected / exposed occurrences (all)	122 / 1257 (9.71%) 167	84 / 966 (8.70%) 106	124 / 974 (12.73%) 159

Influenza			
subjects affected / exposed	69 / 1257 (5.49%)	54 / 966 (5.59%)	59 / 974 (6.06%)
occurrences (all)	88	59	66
Bronchitis			
subjects affected / exposed	52 / 1257 (4.14%)	34 / 966 (3.52%)	33 / 974 (3.39%)
occurrences (all)	54	35	36
Sinusitis			
subjects affected / exposed	30 / 1257 (2.39%)	23 / 966 (2.38%)	20 / 974 (2.05%)
occurrences (all)	33	27	22

<b>Non-serious adverse events</b>	Fasinumab 3mg SC Q4W	Fasinumab 6mg SC Q8W	Fasinumab 6mg SC Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	178 / 214 (83.18%)	1443 / 1677 (86.05%)	95 / 116 (81.90%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	9 / 214 (4.21%)	63 / 1677 (3.76%)	5 / 116 (4.31%)
occurrences (all)	10	77	7
Contusion			
subjects affected / exposed	7 / 214 (3.27%)	62 / 1677 (3.70%)	2 / 116 (1.72%)
occurrences (all)	7	70	2
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 214 (2.80%)	75 / 1677 (4.47%)	2 / 116 (1.72%)
occurrences (all)	7	79	2
Nervous system disorders			
Headache			
subjects affected / exposed	76 / 214 (35.51%)	554 / 1677 (33.04%)	34 / 116 (29.31%)
occurrences (all)	158	1833	124
Paraesthesia			
subjects affected / exposed	13 / 214 (6.07%)	144 / 1677 (8.59%)	6 / 116 (5.17%)
occurrences (all)	18	169	6
Hypoaesthesia			
subjects affected / exposed	11 / 214 (5.14%)	99 / 1677 (5.90%)	5 / 116 (4.31%)
occurrences (all)	14	127	6
Carpal tunnel syndrome			

subjects affected / exposed occurrences (all)	17 / 214 (7.94%) 19	114 / 1677 (6.80%) 133	10 / 116 (8.62%) 11
Dizziness subjects affected / exposed occurrences (all)	7 / 214 (3.27%) 7	94 / 1677 (5.61%) 108	10 / 116 (8.62%) 17
Sciatica subjects affected / exposed occurrences (all)	10 / 214 (4.67%) 10	73 / 1677 (4.35%) 84	6 / 116 (5.17%) 7
General disorders and administration site conditions			
Peripheral swelling subjects affected / exposed occurrences (all)	5 / 214 (2.34%) 6	79 / 1677 (4.71%) 95	3 / 116 (2.59%) 3
Oedema peripheral subjects affected / exposed occurrences (all)	9 / 214 (4.21%) 9	93 / 1677 (5.55%) 110	10 / 116 (8.62%) 10
Gastrointestinal disorders			
Toothache subjects affected / exposed occurrences (all)	11 / 214 (5.14%) 14	118 / 1677 (7.04%) 188	5 / 116 (4.31%) 5
Diarrhoea subjects affected / exposed occurrences (all)	10 / 214 (4.67%) 10	80 / 1677 (4.77%) 87	13 / 116 (11.21%) 19
Nausea subjects affected / exposed occurrences (all)	2 / 214 (0.93%) 3	44 / 1677 (2.62%) 47	5 / 116 (4.31%) 6
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	68 / 214 (31.78%) 107	702 / 1677 (41.86%) 1322	53 / 116 (45.69%) 115
Back pain subjects affected / exposed occurrences (all)	30 / 214 (14.02%) 36	281 / 1677 (16.76%) 515	14 / 116 (12.07%) 24
Pain in extremity subjects affected / exposed occurrences (all)	15 / 214 (7.01%) 29	150 / 1677 (8.94%) 214	20 / 116 (17.24%) 29

Myalgia			
subjects affected / exposed	11 / 214 (5.14%)	101 / 1677 (6.02%)	7 / 116 (6.03%)
occurrences (all)	11	126	7
Osteoarthritis			
subjects affected / exposed	29 / 214 (13.55%)	110 / 1677 (6.56%)	7 / 116 (6.03%)
occurrences (all)	37	140	10
Joint swelling			
subjects affected / exposed	15 / 214 (7.01%)	141 / 1677 (8.41%)	4 / 116 (3.45%)
occurrences (all)	17	181	6
Rapidly progressive osteoarthritis			
subjects affected / exposed	12 / 214 (5.61%)	151 / 1677 (9.00%)	10 / 116 (8.62%)
occurrences (all)	13	187	10
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	43 / 214 (20.09%)	224 / 1677 (13.36%)	12 / 116 (10.34%)
occurrences (all)	55	277	12
Upper respiratory tract infection			
subjects affected / exposed	17 / 214 (7.94%)	219 / 1677 (13.06%)	15 / 116 (12.93%)
occurrences (all)	17	295	18
Urinary tract infection			
subjects affected / exposed	21 / 214 (9.81%)	155 / 1677 (9.24%)	9 / 116 (7.76%)
occurrences (all)	26	208	11
Influenza			
subjects affected / exposed	10 / 214 (4.67%)	103 / 1677 (6.14%)	3 / 116 (2.59%)
occurrences (all)	10	119	3
Bronchitis			
subjects affected / exposed	4 / 214 (1.87%)	71 / 1677 (4.23%)	7 / 116 (6.03%)
occurrences (all)	4	77	7
Sinusitis			
subjects affected / exposed	5 / 214 (2.34%)	71 / 1677 (4.23%)	7 / 116 (6.03%)
occurrences (all)	5	79	8
<b>Non-serious adverse events</b>	Fasinumab 9mg SC Q4W		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 115 (76.52%)		

Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)  Contusion subjects affected / exposed occurrences (all)	4 / 115 (3.48%) 5  8 / 115 (6.96%) 9		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	4 / 115 (3.48%) 4		
Nervous system disorders Headache subjects affected / exposed occurrences (all)  Paraesthesia subjects affected / exposed occurrences (all)  Hypoaesthesia subjects affected / exposed occurrences (all)  Carpal tunnel syndrome subjects affected / exposed occurrences (all)  Dizziness subjects affected / exposed occurrences (all)  Sciatica subjects affected / exposed occurrences (all)	30 / 115 (26.09%) 73  9 / 115 (7.83%) 10  8 / 115 (6.96%) 12  10 / 115 (8.70%) 16  7 / 115 (6.09%) 9  3 / 115 (2.61%) 3		
General disorders and administration site conditions Peripheral swelling subjects affected / exposed occurrences (all)  Oedema peripheral	11 / 115 (9.57%) 11		

subjects affected / exposed	5 / 115 (4.35%)		
occurrences (all)	5		
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	3 / 115 (2.61%)		
occurrences (all)	4		
Diarrhoea			
subjects affected / exposed	4 / 115 (3.48%)		
occurrences (all)	8		
Nausea			
subjects affected / exposed	7 / 115 (6.09%)		
occurrences (all)	7		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	45 / 115 (39.13%)		
occurrences (all)	81		
Back pain			
subjects affected / exposed	13 / 115 (11.30%)		
occurrences (all)	18		
Pain in extremity			
subjects affected / exposed	12 / 115 (10.43%)		
occurrences (all)	42		
Myalgia			
subjects affected / exposed	4 / 115 (3.48%)		
occurrences (all)	4		
Osteoarthritis			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	7		
Joint swelling			
subjects affected / exposed	10 / 115 (8.70%)		
occurrences (all)	12		
Rapidly progressive osteoarthritis			
subjects affected / exposed	8 / 115 (6.96%)		
occurrences (all)	10		
Infections and infestations			



Nasopharyngitis			
subjects affected / exposed	18 / 115 (15.65%)		
occurrences (all)	21		
Upper respiratory tract infection			
subjects affected / exposed	10 / 115 (8.70%)		
occurrences (all)	13		
Urinary tract infection			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	9		
Influenza			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	3 / 115 (2.61%)		
occurrences (all)	4		
Sinusitis			
subjects affected / exposed	3 / 115 (2.61%)		
occurrences (all)	3		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 December 2015	Amendment 1: Added safety and other assessments; Added exclusion criterion
25 February 2016	Amendment 2: Updated reasons for permanent discontinuation of study drug; Updated inclusion and exclusion criteria
20 June 2016	Amendment 3: Updated the dose selection, randomization ratio and permitted and prohibited therapy information; Added risk-benefit assessment; Updated and added inclusion criteria; Added chemistry and hematology safety labs and other tests
25 August 2016	Amendment 4: Updated laboratory and urine collection timepoints and added other tests to better monitor subject safety during the trial
17 January 2017	Amendment 5: Updated Rationale for Dose Selection; Minor edits and clarifications were made
16 March 2017	Amendment 6: Update the doses, dosing schedule, and rationale for dose selection; Added an end of study phone contact at 52 weeks following the last dose of study drug; Updated enrollment number and the randomization allocation; Updated the language referring to stopping guidelines for a dose arm, the study or the program; Clarified safety objectives and updated associated endpoints and statistical methods; Simplified the efficacy sub-study objective and updated the associated endpoints and statistical methods; Added an end of study definition; Updated the exclusion criterion; Added additional inclusion and exclusion criteria for the efficacy sub-study; Added additional reasons for permanent discontinuation of study drug; Added a PK sample collection timepoints
24 May 2018	Amendment 7: Incorporated an urgent safety measure
11 July 2018	Amendment 8: Purpose was to gain greater safety exposure to the fasinumab 1 mg dose in the main safety study

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported