



## Clinical trial results:

### A Multicenter, International, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Assess the Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis

#### Summary

EudraCT number	2011-001456-11
Trial protocol	HU BE DK PL DE GB EE CZ ES LV LT
Global end of trial date	28 December 2016

#### Results information

Result version number	v1 (current)
This version publication date	03 January 2018
First version publication date	03 January 2018

#### Trial information

##### Trial identification

Sponsor protocol code	20070337
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01575834
WHO universal trial number (UTN)	-

Notes:

##### Sponsors

Sponsor organisation name	Amgen Inc
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States, 91320
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.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
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Date of interim/final analysis	28 December 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 December 2016
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is to determine if treatment with romosozumab is effective in preventing fractures in women with postmenopausal osteoporosis

Protection of trial subjects:

This study was conducted in accordance with applicable local, Food and Drug Administration, and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines. The study protocol, subject information, and informed consent form were reviewed and approved by the independent ethics committee (IEC) or institutional review board (IRB) for each study center. All subjects provided written informed consent before any protocol-specific screening procedures or any investigational products were administered and after the aims, methods, anticipated benefits, and potential hazards of the study were adequately explained.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 March 2012
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	Spain: 61
Country: Number of subjects enrolled	Switzerland: 34
Country: Number of subjects enrolled	United Kingdom: 398
Country: Number of subjects enrolled	United States: 132
Country: Number of subjects enrolled	Argentina: 177
Country: Number of subjects enrolled	Australia: 25
Country: Number of subjects enrolled	Belgium: 26
Country: Number of subjects enrolled	Brazil: 816
Country: Number of subjects enrolled	Canada: 63
Country: Number of subjects enrolled	Colombia: 1822
Country: Number of subjects enrolled	Czech Republic: 334
Country: Number of subjects enrolled	Denmark: 334
Country: Number of subjects enrolled	Dominican Republic: 173
Country: Number of subjects enrolled	Estonia: 110
Country: Number of subjects enrolled	Germany: 67
Country: Number of subjects enrolled	Hong Kong: 231
Country: Number of subjects enrolled	Hungary: 203
Country: Number of subjects enrolled	India: 106
Country: Number of subjects enrolled	Japan: 492
Country: Number of subjects enrolled	Latvia: 51
Country: Number of subjects enrolled	Lithuania: 112

Country: Number of subjects enrolled	Mexico: 96
Country: Number of subjects enrolled	New Zealand: 34
Country: Number of subjects enrolled	Poland: 1241
Country: Number of subjects enrolled	Romania: 42
Worldwide total number of subjects	7180
EEA total number of subjects	2979

Notes:

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### Subjects enrolled per age group

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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)	1525
From 65 to 84 years	5439
85 years and over	216

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted at 222 centers in Europe, Central/Latin America, Asia, North America, and Australia/New Zealand.

The first participant enrolled on 15 March 2012 and the last participant enrolled on 06 December 2013.

### Pre-assignment

Screening details:

Participants were randomized 1:1 to receive either romosozumab 210 mg or matched placebo for the 12-month, double-blind, placebo-controlled period. Randomization was stratified by age (< 75 years, ≥ 75 years) and prevalent vertebral fracture (yes, no), as determined by site staff at randomization based on local reading of the spine X-ray.

### 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	Subject, Investigator

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Placebo/Denosumab

Arm description:

Participants received placebo subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.

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

Dosage and administration details:

Administered by subcutaneous injection once a month

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

Dosage and administration details:

Administered by subcutaneous injection once every 6 months

<b>Arm title</b>	Romosozumab/Denosumab
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Arm description:

Participants received romosozumab 210 mg subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.

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

Dosage and administration details:

Administered by subcutaneous injection once every 6 months

Investigational medicinal product name	Romosozumab
Investigational medicinal product code	AMG 785
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection once a month

<b>Number of subjects in period 1</b>	Placebo/Denosumab	Romosozumab/Denosumab
Started	3591	3589
Received Double-blind Treatment	3582	3575
Completed Double-blind Period	3205	3185
Completed 24-month Study Period	3032	2994
Completed	2892	2851
Not completed	699	738
Death	81	74
Other	70	70
Requirement for alternative therapy	2	4
Noncompliance	52	27
Administrative decision	15	33
Ineligibility determined	5	8
Adverse event, non-fatal	63	61
Consent withdrawn by subject	352	390
Protocol deviation	4	3
Lost to follow-up	55	68

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo/Denosumab
Reporting group description:	
Participants received placebo subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.	
Reporting group title	Romosozumab/Denosumab
Reporting group description:	
Participants received romosozumab 210 mg subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.	

Reporting group values	Placebo/Denosumab	Romosozumab/Denosumab	Total
Number of subjects	3591	3589	7180
Age Categorical Units: Subjects			
Adults (18-64 years)	757	768	1525
From 65-84 years	2727	2712	5439
85 years and over	107	109	216
Age Continuous Units: years			
arithmetic mean	70.8	70.9	
standard deviation	± 6.9	± 7.0	-
Gender Categorical Units: Subjects			
Female	3591	3589	7180
Male	0	0	0
Race Units: Subjects			
White	2052	2063	4115
Asian	441	425	866
Black or African American	74	77	151
American Indian/Alaska Native	63	64	127
Native Hawaiian/Other Pacific Islander	1	0	1
Multiple	59	60	119
Other	901	900	1801
Ethnicity Units: Subjects			
Hispanic or Latino	1416	1427	2843
Not Hispanic or Latino	2175	2162	4337
Prevalent Vertebral Fracture Strata per Randomization			
Strata per randomization for prevalent fracture were based on local reading of baseline spine radiographs.			
Units: Subjects			
Yes	205	204	409
No	3386	3385	6771
Age Strata per Randomization Units: Subjects			

< 75 years	2471	2470	4941
≥ 75 years	1120	1119	2239

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## End points

### End points reporting groups

Reporting group title	Placebo/Denosumab
Reporting group description:	
Participants received placebo subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.	
Reporting group title	Romosozumab/Denosumab
Reporting group description:	
Participants received romosozumab 210 mg subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.	

### Primary: Percentage of Participants with New Vertebral Fracture Through Month 12

End point title	Percentage of Participants with New Vertebral Fracture Through Month 12
End point description:	
New vertebral fractures occurred when there was $\geq 1$ grade increase from the previous grade of 0 in any vertebra from T4 to L4 using the Genant semiquantitative scoring method. The Genant semiquantitative scoring method was based on assessment of x-rays according to the following scale:	
<ul style="list-style-type: none"><li>• Grade 0 (Normal) = no fracture;</li><li>• Grade 1 (Mild) = mild fracture, 20 to 25% reduction in vertebral height (anterior, middle, or posterior);</li><li>• Grade 2 (Moderate) = moderate fracture, 25 to 40% reduction in anterior, middle, and/or posterior height;</li><li>• Grade 3 (Severe) = severe fracture, &gt; 40% reduction in anterior, middle, and/or posterior height.</li></ul>	
The primary analysis set for vertebral fractures includes all subjects with a baseline and $\geq 1$ postbaseline evaluation of vertebral fracture during the 12 months, including subjects with missing baseline Genant scores whose first postbaseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.	
End point type	Primary
End point timeframe:	
12 months	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3322	3321		
Units: percentage of participants				
number (not applicable)	1.8	0.5		

### Statistical analyses

Statistical analysis title	Analysis of New Vertebral Fracture To Month 12
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6643
Analysis specification	Pre-specified
Analysis type	superiority <sup>[1]</sup>



P-value	< 0.001 <sup>[2]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	0.47

Notes:

[1] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[2] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test.

### Primary: Percentage of Participants with New Vertebral Fracture Through Month 24

End point title	Percentage of Participants with New Vertebral Fracture Through Month 24
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End point description:

New vertebral fractures occurred when there was  $\geq 1$  grade increase from the previous grade of 0 in any vertebra from T4 to L4 using the Genant semiquantitative scoring method.

The Genant semiquantitative scoring method was based on assessment of x-rays according to the following scale:

- Grade 0 (Normal) = no fracture;
- Grade 1 (Mild) = mild fracture, 20 to 25% reduction in vertebral height (anterior, middle, or posterior);
- Grade 2 (Moderate) = moderate fracture, 25 to 40% reduction in anterior, middle, and/or posterior height;
- Grade 3 (Severe) = severe fracture, > 40% reduction in anterior, middle, and/or posterior height.

The primary analysis set for vertebral fractures includes all subjects with a baseline and  $\geq 1$  postbaseline evaluation of vertebral fracture during the 24 months, including subjects with missing baseline Genant scores whose first postbaseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.

End point type	Primary
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End point timeframe:

24 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3327	3325		
Units: percentage of participants				
number (not applicable)	2.5	0.6		

### Statistical analyses

Statistical analysis title	Analysis of New Vertebral Fracture To Month 24
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6652
Analysis specification	Pre-specified
Analysis type	superiority <sup>[3]</sup>
P-value	< 0.001 <sup>[4]</sup>

Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	0.39

Notes:

[3] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[4] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test.

## Secondary: Percentage of Participants with a Clinical Fracture Through Month 12

End point title	Percentage of Participants with a Clinical Fracture Through Month 12
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End point description:

Clinical fractures included clinical vertebral and nonvertebral fractures (excluding skull, facial, mandible, cervical vertebrae, thoracic vertebrae, lumbar vertebrae, metacarpus, finger phalanges, and toe phalanges) that were associated with signs and/or symptoms indicative of a fracture. Clinical vertebral fractures were included regardless of trauma severity or pathologic fractures; nonvertebral fractures associated with high trauma severity or pathologic fractures were excluded.

The full analysis set consisted of all randomized participants. Last observation carried forward imputation (LOCF) was used for this analysis.

End point type	Secondary
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End point timeframe:

12 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	2.5	1.6		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Clinical Fracture Through Month 12
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[5]</sup>
P-value	= 0.008 <sup>[6]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided

lower limit	0.46
upper limit	0.89

Notes:

[5] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[6] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Nonvertebral Fracture Through Month 12

End point title	Percentage of Participants with a Nonvertebral Fracture Through Month 12
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End point description:

A nonvertebral fracture was defined as a fracture present on a copy of radiographs or other diagnostic images such as computerized tomography (CT) or magnetic resonance imaging confirming the fracture within 14 days of reported fracture image date recorded by the study site, and/or documented in a copy of the radiology report, surgical report, or discharge summary, excluding skull, facial, mandible, cervical vertebrae, thoracic vertebrae, lumbar vertebrae, metacarpus, finger phalanges, and toe phalanges. In addition, fractures associated with high trauma severity or pathologic fractures were excluded. The full analysis set was used for this analysis.

End point type	Secondary
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End point timeframe:

12 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	2.1	1.6		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Nonvertebral Fracture Through Month 12
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[7]</sup>
P-value	= 0.096 <sup>[8]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.05

Notes:

[7] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

## Secondary: Percentage of Participants with a Nonvertebral Fracture Through Month 24

End point title	Percentage of Participants with a Nonvertebral Fracture Through Month 24
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End point description:

A nonvertebral fracture was defined as a fracture present on a copy of radiographs or other diagnostic images such as computerized tomography (CT) or magnetic resonance imaging confirming the fracture within 14 days of reported fracture image date as recorded by the study site, and/or documented in a copy of the radiology report, surgical report, or discharge summary, excluding skull, facial, mandible, cervical vertebrae, thoracic vertebrae, lumbar vertebrae, metacarpus, finger phalanges, and toe phalanges. In addition, fractures associated with high trauma severity or pathologic fractures were excluded.

The full analysis set was used for the analysis.

End point type	Secondary
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End point timeframe:

24 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	3.6	2.7		

## Statistical analyses

Statistical analysis title	Analysis of Nonvertebral Fracture Through Month 24
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[9]</sup>
P-value	= 0.057 <sup>[10]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.97

Notes:

[9] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[10] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Clinical Fracture Through Month 24

End point title	Percentage of Participants with a Clinical Fracture Through Month 24
End point description: Clinical fractures included clinical vertebral and nonvertebral fractures (excluding skull, facial, mandible, cervical vertebrae, thoracic vertebrae, lumbar vertebrae, metacarpus, finger phalanges, and toe phalanges) that were associated with signs and/or symptoms indicative of a fracture. Clinical vertebral fractures were included regardless of trauma severity or pathologic fractures; nonvertebral fractures associated with high trauma severity or pathologic fractures were excluded. The full analysis set with LOCF imputation was used in the analysis.	
End point type	Secondary
End point timeframe: 24 months	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	4.1	2.8		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Clinical Fracture Through Month 24
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[11]</sup>
P-value	= 0.096 <sup>[12]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.87

Notes:

[11] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[12] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Major Nonvertebral Fracture Through Month 12

End point title	Percentage of Participants with a Major Nonvertebral Fracture Through Month 12
End point description: A major nonvertebral fracture was a subset of nonvertebral fractures including pelvis, distal femur (ie, femur excluding hip), proximal tibia (ie, tibia excluding ankle), ribs, proximal humerus (ie, humerus excluding elbow), forearm, and hip. The full analysis set was used for the analysis.	

End point type	Secondary
End point timeframe:	
12 months	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	1.5	1.0		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Major Nonvertebral Fracture
Statistical analysis description:	
Analysis of major nonvertebral fracture through month 12	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[13]</sup>
P-value	= 0.096 <sup>[14]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	1.02

Notes:

[13] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[14] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Major Nonvertebral Fracture Through Month 24

End point title	Percentage of Participants with a Major Nonvertebral Fracture Through Month 24
End point description:	
A major nonvertebral fracture was a subset of nonvertebral fractures including pelvis, distal femur (ie, femur excluding hip), proximal tibia (ie, tibia excluding ankle), ribs, proximal humerus (ie, humerus excluding elbow), forearm, and hip.	
The full analysis set was used for the analysis.	
End point type	Secondary
End point timeframe:	
24 months	

<b>End point values</b>	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	2.8	1.9		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Major Nonvertebral Fracture
Statistical analysis description:	
Analysis of major nonvertebral fracture through month 24	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[15]</sup>
P-value	= 0.096 <sup>[16]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.91

Notes:

[15] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[16] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a New or Worsening Vertebral Fracture Through Month 12

<b>End point title</b>	Percentage of Participants with a New or Worsening Vertebral Fracture Through Month 12
End point description:	
A new or worsening vertebral fracture was identified when there was a $\geq 1$ grade increase from the previous grade in any vertebra from T4 to L4.	
The primary analysis set for vertebral fractures with LOCF imputation was used for the analysis.	
End point type	Secondary
End point timeframe:	
12 months	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3322	3321		
Units: percentage of participants				
number (not applicable)	1.8	0.5		

## Statistical analyses

Statistical analysis title	Analysis of New or Worsening Vertebral Fracture
Statistical analysis description:	
Analysis of new or worsening vertebral fracture through month 12	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6643
Analysis specification	Pre-specified
Analysis type	superiority <sup>[17]</sup>
P-value	= 0.096 <sup>[18]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	0.49

Notes:

[17] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[18] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test.

## Secondary: Percentage of Participants with a New or Worsening Vertebral Fracture Through Month 24

End point title	Percentage of Participants with a New or Worsening Vertebral Fracture Through Month 24
End point description:	
A new or worsening vertebral fracture was identified when there was a $\geq 1$ grade increase from the previous grade in any vertebra from T4 to L4.	
The primary analysis set for vertebral fractures with LOCF imputation was used in the analysis.	
End point type	Secondary
End point timeframe:	
24 months	



End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3327	3325		
Units: percentage of participants				
number (not applicable)	2.5	0.7		

## Statistical analyses

Statistical analysis title	Analysis of New or Worsening Vertebral Fracture
Statistical analysis description:	
Analysis of new or worsening vertebral fracture through month 24	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6652
Analysis specification	Pre-specified
Analysis type	superiority <sup>[19]</sup>
P-value	= 0.096 <sup>[20]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.41

Notes:

[19] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[20] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test

## Secondary: Percentage of Participants with a Hip Fracture Through Month 12

End point title	Percentage of Participants with a Hip Fracture Through Month 12
End point description:	
Hip fractures were defined as a subset of nonvertebral fractures including fractures of the femur neck, femur intertrochanter, and femur subtrochanter.	
The full analysis set was used for this analysis.	
End point type	Secondary
End point timeframe:	
12 months	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	0.4	0.2		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Hip Fracture Through Month 12
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[21]</sup>
P-value	= 0.18 <sup>[22]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	1.35

Notes:

[21] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[22] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Hip Fracture Through Month 24

End point title	Percentage of Participants with a Hip Fracture Through Month 24
End point description:	
Hip fractures were defined as a subset of nonvertebral fractures including fractures of the femur neck, femur intertrochanter, and femur subtrochanter. The full analysis set was used for this analysis.	
End point type	Secondary
End point timeframe:	
24 months	

<b>End point values</b>	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	0.6	0.3		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Hip Fracture Through Month 24
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority <sup>[23]</sup>
P-value	= 0.12 <sup>[24]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	1.04

Notes:

[23] - A fixed-sequence testing procedure was used for multiplicity adjustment of the coprimary and a subset of secondary efficacy endpoints to maintain the overall significance level at 0.05.

[24] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Major Osteoporotic Fracture Through Month 12

End point title	Percentage of Participants with a Major Osteoporotic Fracture Through Month 12
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End point description:

Major osteoporotic fractures included hip, forearm, or humerus fractures that were not associated with a pathologic fracture regardless of trauma severity, and clinical vertebral fractures.

The full analysis set was used for this analysis.

End point type	Secondary
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End point timeframe:

12 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	1.8	1.1		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Major Osteoporotic Fracture
Statistical analysis description:	
Analysis of major osteoporotic fracture through month 12	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 <sup>[25]</sup>

Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.9

Notes:

[25] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with a Major Osteoporotic Fracture Through Month 24

End point title	Percentage of Participants with a Major Osteoporotic Fracture Through Month 24
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End point description:

Major osteoporotic fractures included hip, forearm, or humerus fractures that were not associated with a pathologic fracture regardless of trauma severity, and clinical vertebral fractures. The full analysis set was used for this analysis.

End point type	Secondary
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End point timeframe:

24 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3591	3589		
Units: percentage of participants				
number (not applicable)	3.1	1.9		

## Statistical analyses

Statistical analysis title	Analysis of Major Osteoporotic Fracture
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Statistical analysis description:

Analysis of major osteoporotic fracture through month 24

Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	7180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 <sup>[26]</sup>
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46

upper limit	0.84
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Notes:

[26] - Cox proportional hazards model adjusting for age and prevalent vertebral fracture stratification variables.

## Secondary: Percentage of Participants with Multiple New or Worsening Vertebral Fractures Through Month 12

End point title	Percentage of Participants with Multiple New or Worsening Vertebral Fractures Through Month 12
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End point description:

A new or worsening vertebral fracture was identified when there was a  $\geq 1$  grade increase from the previous grade in any vertebra from T4 to L4. A participant had multiple new or worsening vertebral fractures when there were  $\geq 2$  vertebrae from T4 to L4 with  $\geq 1$  grade increase from the previous grade. The multiple new or worsening vertebral fractures need not have occurred at the same visit. The primary analysis set for vertebral fractures with LOCF imputation was used for the analysis.

End point type	Secondary
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End point timeframe:

12 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3322	3321		
Units: percentage of participants				
number (not applicable)	0.3	0.03		

## Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Analysis of multiple new or worsening vertebral fractures through month 12

Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6643
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011 [27]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.87

Notes:

[27] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test.

## Secondary: Percentage of Participants with Multiple New or Worsening Vertebral

## Fractures Through Month 24

End point title	Percentage of Participants with Multiple New or Worsening Vertebral Fractures Through Month 24
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End point description:

A new or worsening vertebral fracture was identified when there was a  $\geq 1$  grade increase from the previous grade in any vertebra from T4 to L4. A participant had multiple new or worsening vertebral fractures when there were  $\geq 2$  vertebrae from T4 to L4 with  $\geq 1$  grade increase from the previous grade. The multiple new or worsening vertebral fractures need not have occurred at the same visit. The primary analysis set for vertebral fractures with LOCF imputation was used in the analysis.

End point type	Secondary
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End point timeframe:

24 months

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3327	3325		
Units: percentage of participants				
number (not applicable)	0.5	0.03		

## Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Analysis of multiple new or worsening vertebral fractures through month 24

Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
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Number of subjects included in analysis	6652
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	$< 0.001$ <sup>[28]</sup>
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Method	Regression, Logistic
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Parameter estimate	Odds ratio (OR)
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Point estimate	0.06
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.01
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upper limit	0.44
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Notes:

[28] - Based on logistic regression model adjusted for age and prevalent vertebral fracture stratification variables; p-value based on score test.

## Secondary: Percent Change from Baseline in Bone Mineral Density at the Lumbar Spine at Month 12

End point title	Percent Change from Baseline in Bone Mineral Density at the Lumbar Spine at Month 12
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End point description:

Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.

The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and  $\geq 1$  post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used.

End point type	Secondary
End point timeframe:	
Baseline and month 12	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3148	3151		
Units: percent change				
least squares mean (standard error)	0.4 ( $\pm$ 0.1)	13.1 ( $\pm$ 0.1)		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Lumbar Spine BMD at Month 12
Statistical analysis description:	
The treatment comparison of BMD at the lumbar spine was analyzed using an analysis of covariance (ANCOVA) model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	12.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	12.9
Variability estimate	Standard error of the mean
Dispersion value	0.1

## Secondary: Percent Change from Baseline In Bone Mineral Density at the Lumbar Spine at Month 24

End point title	Percent Change from Baseline In Bone Mineral Density at the Lumbar Spine at Month 24
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End point description:

Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.

The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and  $\geq 1$  post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used in the analysis.

End point type	Secondary
End point timeframe:	
Baseline and Month 24	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2877	2861		
Units: percent change				
least squares mean (standard error)	5.5 (± 0.1)	16.6 (± 0.1)		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Lumbar Spine BMD at Month 24
Statistical analysis description:	
The treatment comparison of BMD at the lumbar spine was analyzed using an analysis of covariance (ANCOVA) model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	5738
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.8
upper limit	11.4
Variability estimate	Standard error of the mean
Dispersion value	0.1

## Secondary: Percent Change from Baseline in Bone Mineral Density at the Total Hip at Month 12

End point title	Percent Change from Baseline in Bone Mineral Density at the Total Hip at Month 12
End point description:	
Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.	
The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and ≥ 1 post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used in the analysis.	
End point type	Secondary
End point timeframe:	



<b>End point values</b>	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3210	3197		
Units: percent change				
least squares mean (standard error)	0.3 ( $\pm$ 0.1)	6.0 ( $\pm$ 0.1)		

### Statistical analyses

<b>Statistical analysis title</b>	Analysis of Total Hip BMD at Month 12
Statistical analysis description:	
The treatment comparison of BMD at the total hip was analyzed using an ANCOVA model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6407
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.6
upper limit	6
Variability estimate	Standard error of the mean
Dispersion value	0.1

### Secondary: Percent Change from Baseline in Bone Mineral Density at the Total Hip at Month 24

End point title	Percent Change from Baseline in Bone Mineral Density at the Total Hip at Month 24
End point description:	
Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.	
The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and $\geq$ 1 post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used.	
End point type	Secondary
End point timeframe:	
Baseline and month 24	

<b>End point values</b>	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2918	2903		
Units: percent change				
least squares mean (standard error)	3.2 ( $\pm$ 0.1)	8.5 ( $\pm$ 0.1)		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Total Hip BMD at Month 24
Statistical analysis description:	
The treatment comparison of BMD at the total hip was analyzed using an ANCOVA model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	5821
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.1
upper limit	5.5
Variability estimate	Standard error of the mean
Dispersion value	0.1

## Secondary: Percent Change from Baseline in Bone Mineral Density at the Femoral Neck at Month 12

<b>End point title</b>	Percent Change from Baseline in Bone Mineral Density at the Femoral Neck at Month 12
End point description:	
Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.	
The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and $\geq$ 1 post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used in the analysis.	
End point type	Secondary
End point timeframe:	
Baseline and month 12	

End point values	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3210	3197		
Units: percent change				
least squares mean (standard error)	0.3 ( $\pm$ 0.1)	5.5 ( $\pm$ 0.1)		

## Statistical analyses

Statistical analysis title	Analysis of Femoral Neck BMD at Month 12
Statistical analysis description:	
The treatment comparison of BMD at the femoral neck was analyzed using an ANCOVA model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	6407
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.9
upper limit	5.4
Variability estimate	Standard error of the mean
Dispersion value	0.1

## Secondary: Percent Change from Baseline in Bone Mineral Density at the Femoral Neck at Month 24

End point title	Percent Change from Baseline in Bone Mineral Density at the Femoral Neck at Month 24
End point description:	
Bone mineral density (BMD) was measured by dual-energy x-ray absorptiometry (DXA). DXA scans were analyzed by a central imaging center.	
The primary efficacy analysis set for BMD includes all randomized participants who had a baseline and $\geq$ 1 post-baseline evaluation at or before the time point under consideration in the study period; LOCF imputation was used in the analysis.	
End point type	Secondary
End point timeframe:	
Baseline and month 24	

<b>End point values</b>	Placebo/Denosumab	Romosozumab/Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2918	2903		
Units: percent change				
least squares mean (standard error)	2.3 ( $\pm$ 0.1)	7.3 ( $\pm$ 0.1)		

## Statistical analyses

<b>Statistical analysis title</b>	Analysis of Femoral Neck BMD at Month 24
Statistical analysis description:	
The treatment comparison of BMD at the femoral neck was analyzed using an ANCOVA model which included treatment, age and prevalent vertebral fracture stratification variables, and baseline value of the endpoint, machine type and machine type-by-baseline value interaction.	
Comparison groups	Placebo/Denosumab v Romosozumab/Denosumab
Number of subjects included in analysis	5821
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	5.2
Variability estimate	Standard error of the mean
Dispersion value	0.1

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Double-blind treatment period: 12 months;

Overall study: 36 months

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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### Reporting groups

Reporting group title	12-Month Double-blind Period: Placebo
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Reporting group description:

Participants received placebo subcutaneous injections once a month for 12 months.

Reporting group title	12-Month Double-blind Period: Romosozumab
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Reporting group description:

Participants received romosozumab 210 mg subcutaneous injections once a month for 12 months.

Reporting group title	36-Month Study Period: Placebo/Denosumab
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Reporting group description:

Participants received placebo subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.

Reporting group title	36-Month Study Period: Romosozumab/Denosumab
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Reporting group description:

Participants received romosozumab 210 mg subcutaneous injections once a month for 12 months, followed by 60 mg denosumab subcutaneously once every 6 months for 24 months.

Serious adverse events	12-Month Double-blind Period: Placebo	12-Month Double-blind Period: Romosozumab	36-Month Study Period: Placebo/Denosumab
Total subjects affected by serious adverse events			
subjects affected / exposed	314 / 3576 (8.78%)	344 / 3581 (9.61%)	733 / 3576 (20.50%)
number of deaths (all causes)	24	29	85
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acetabulum fracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 contusion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Cataract operation complication			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Eye injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	8 / 3576 (0.22%)	3 / 3581 (0.08%)	14 / 3576 (0.39%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	19 / 3576 (0.53%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	8 / 3576 (0.22%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	8 / 3576 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Joint dislocation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 concussion syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Postoperative adhesion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Postoperative delirium			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 hypotension			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radial head dislocation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	5 / 3576 (0.14%)	3 / 3581 (0.08%)	17 / 3576 (0.48%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site ischaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Subdural haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	12 / 3576 (0.34%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine dehiscence			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 evisceration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound necrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood lactic acid increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to	0 / 0	0 / 0	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 pressure increased			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body mass index increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pH decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 enzyme increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 B virus test positive subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute myocardial infarction subjects affected / exposed	4 / 3576 (0.11%)	6 / 3581 (0.17%)	10 / 3576 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Adams-Stokes syndrome subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Angina unstable subjects affected / exposed	3 / 3576 (0.08%)	6 / 3581 (0.17%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 9

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease mixed subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation subjects affected / exposed	4 / 3576 (0.11%)	6 / 3581 (0.17%)	18 / 3576 (0.50%)
occurrences causally related to treatment / all	0 / 4	0 / 8	1 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Bradycardia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 arrest			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 3
Cardiac failure			
subjects affected / exposed	1 / 3576 (0.03%)	5 / 3581 (0.14%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac failure acute			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac failure chronic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	4 / 3576 (0.11%)	7 / 3581 (0.20%)	8 / 3576 (0.22%)
occurrences causally related to treatment / all	1 / 4	0 / 8	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 5
Cardiogenic shock			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiopulmonary failure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Congestive cardiomyopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Cor pulmonale			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	3 / 3576 (0.08%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart valve incompetence			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low cardiac output syndrome subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve stenosis subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 3
Myocardial ischaemia subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paroxysmal atrioventricular block subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sinus bradycardia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anaemia of chronic disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplastic anaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocoagulable state			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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			
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arachnoid cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia stroke			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem ischaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to	0 / 1	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar ischaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 infarction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Cerebrovascular disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicogenic headache			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Dementia Alzheimer's type			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Depressed level of consciousness			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic coma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dizziness			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolus cerebral infarction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhagic transformation stroke subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 encephalopathy subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal carotid artery kinking			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 cerebral infarction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lacunar infarction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Meralgia paraesthetica			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor dysfunction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis relapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve root compression			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis recurrent laryngeal nerve			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 herpetic neuralgia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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-traumatic headache			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Sciatica			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stupor			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Trigeminal neuralgia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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			
Age-related macular degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angle closure glaucoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	5 / 3576 (0.14%)	4 / 3581 (0.11%)	14 / 3576 (0.39%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystoid macular oedema			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior capsule rupture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness unilateral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoacusis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)



occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniere's disease			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular ataxia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	3 / 3576 (0.08%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences causally related to	0 / 3	1 / 4	0 / 9

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 gastritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enteritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of small intestine			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 polyps			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal hypomotility			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial eventration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 umbilical hernia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intestinal ischaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Intestinal obstruction			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal perforation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 intestinal ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

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 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst rupture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic fistula			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal adhesions			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reflux gastritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestinal perforation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toothache			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute prerenal failure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 kidney disease			

subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocalyx			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 failure			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal impairment			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric perforation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 incontinence			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to	0 / 0	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma annulare			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ingrowing nail			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen sclerosus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash macular			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.03%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coccydynia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 pain			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 compression			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 protrusion			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal degeneration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)



occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis deformans			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	15 / 3576 (0.42%)	6 / 3581 (0.17%)	27 / 3576 (0.76%)
occurrences causally related to treatment / all	0 / 15	0 / 7	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 of jaw			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 jaw			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Spinal column stenosis			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	10 / 3576 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Systemic lupus erythematosus subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary hyperaldosteronism subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dehydration subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folate deficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochloraemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoosmolar state			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mineral metabolism disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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			
Abdominal sepsis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Abscess			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic colitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	7 / 3576 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bacterial tracheitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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	2 / 3576 (0.06%)	5 / 3581 (0.14%)	11 / 3576 (0.31%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chikungunya virus infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chlamydial infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 sinusitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dermatitis infected			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)



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	3 / 3576 (0.08%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphyema			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Enterobacter bacteraemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis viral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infected dermal cyst				
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Infected skin ulcer				
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis				
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)	
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 chronic obstructive airways disease				
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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	
Influenza				
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Intestinal gangrene				
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Labyrinthitis				
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Liver abscess				
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)	
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 respiratory tract infection				

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site joint infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perichondritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis infective			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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			
subjects affected / exposed	10 / 3576 (0.28%)	19 / 3581 (0.53%)	37 / 3576 (1.03%)
occurrences causally related to treatment / all	0 / 11	1 / 24	0 / 44
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pneumonia bacterial			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cryptococcal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 haemophilus			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 mycoplasmal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelocystitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyelonephritis acute			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyometra			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyonephrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tick-borne viral encephalitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	7 / 3576 (0.20%)	4 / 3581 (0.11%)	14 / 3576 (0.39%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 4



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginitis bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound abscess			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Deep vein thrombosis			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Dry gangrene			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.14%)	8 / 3581 (0.22%)	12 / 3576 (0.34%)
occurrences causally related to treatment / all	0 / 7	0 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pelvic venous thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 artery stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 artery thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Peripheral ischaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 ulceration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cardiac pacemaker replacement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to	0 / 0	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterectomy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteosynthesis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 resection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rehabilitation therapy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar excision			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acral lentiginous melanoma			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 gastric			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	8 / 3576 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 4
Adenocarcinoma of colon			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal cancer			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiocentric lymphoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	5 / 3576 (0.14%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basosquamous carcinoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign breast neoplasm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastric neoplasm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of adrenal gland			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of spinal cord			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Benign pleural neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign salivary gland neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign soft tissue neoplasm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Breast cancer			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	11 / 3576 (0.31%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Breast cancer female			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)



occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer recurrent			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage III			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cervix carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cervix carcinoma stage II			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroid melanoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (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
Colon cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fibrous histiocytoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 cancer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granular cell tumour			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine benign neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	6 / 3576 (0.17%)	7 / 3581 (0.20%)	10 / 3576 (0.28%)
occurrences causally related to treatment / all	2 / 7	0 / 7	2 / 13

deaths causally related to treatment / all	0 / 0	0 / 4	0 / 1
Lymphoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 neoplasm of conjunctiva			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metastases to lymph nodes			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 pleura			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngeal cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm of appendix			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 carcinoma of the skin			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurofibroma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 carcinoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 squamous cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 squamous cell carcinoma recurrent			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 adenoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ovarian cancer metastatic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paget's disease of nipple			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancoast's tumour			

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Pancreatic neuroendocrine tumour			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal sinus benign neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phaeochromocytoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic granuloma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)



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 adenocarcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 cancer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer stage II			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 adenoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 cell lung cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 intestine adenocarcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 intestine carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of pharynx			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tracheal cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immobile			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
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	5 / 3576 (0.14%)	5 / 3581 (0.14%)	9 / 3576 (0.25%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 5	0 / 9
General physical health deterioration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal dryness			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 3

Non-cardiac chest pain			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 4
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 withdrawal syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Personality change due to a general medical condition			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudodementia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophreniform disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient psychosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical polyp			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

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 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 hyperplasia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrocystic breast disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pelvic haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	5 / 3581 (0.14%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal polyp			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 distress syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolitis allergic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchiectasis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choking sensation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	15 / 3576 (0.42%)	6 / 3581 (0.17%)	28 / 3576 (0.78%)
occurrences causally related to treatment / all	0 / 18	0 / 6	0 / 35
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Dyspnoea exertional			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary mass			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 distress			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Sinus polyp			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis sclerosing			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholecystitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences causally related to	0 / 1	0 / 3	0 / 6

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (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
Cholelithiasis			
subjects affected / exposed	8 / 3576 (0.22%)	5 / 3581 (0.14%)	11 / 3576 (0.31%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis obstructive			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
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 failure			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hepatic steatosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
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 injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sphincter of Oddi dysfunction subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	36-Month Study Period: Romosozumab/Deno sumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	728 / 3581 (20.33%)		
number of deaths (all causes)	72		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cataract operation complication			
subjects affected / exposed	1 / 3581 (0.03%)		



occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Eye injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyelid injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	7 / 3581 (0.20%)			
occurrences causally related to treatment / all	0 / 7			

deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	11 / 3581 (0.31%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	9 / 3581 (0.25%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	7 / 3581 (0.20%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foreign body				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured sacrum				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal stoma complication				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Head injury				
subjects affected / exposed	6 / 3581 (0.17%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	8 / 3581 (0.22%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Internal injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Limb injury				
subjects affected / exposed	1 / 3581 (0.03%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle rupture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle strain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Post concussion syndrome				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Postoperative adhesion				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Postoperative delirium				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural complication				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural hypotension				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pubis fracture				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radial head dislocation				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	14 / 3581 (0.39%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sternal fracture				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stoma site ischaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	1 / 3581 (0.03%)			

occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Subdural haematoma			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Uterine dehiscence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Wound complication			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound necrosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood lactic acid increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Body mass index increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0			
Fibrin D dimer increased				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric pH decreased				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical condition abnormal				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoglobin decreased				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza B virus test positive				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			

Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 2		
Adams-Stokes syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Angina unstable			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Aortic valve disease mixed			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arrhythmia supraventricular			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Cardiac failure			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 1		
Cardiac failure acute			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Cardiac failure chronic			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Cardiac failure congestive			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Cardio-respiratory arrest			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 3		
Cardiogenic shock			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiopulmonary failure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Congestive cardiomyopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cor pulmonale			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 7		

deaths causally related to treatment / all	0 / 0			
Coronary artery insufficiency subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Heart valve incompetence subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive heart disease subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic cardiomyopathy subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Low cardiac output syndrome subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mitral valve prolapse subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mitral valve stenosis subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Myocardial infarction				
subjects affected / exposed	8 / 3581 (0.22%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 3			
Myocardial ischaemia				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paroxysmal atrioventricular block				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prinzmetal angina				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	1 / 3581 (0.03%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Anaemia of chronic disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aplastic anaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypocoagulable state			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pernicious anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 3581 (0.03%)		



occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arachnoid cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal ganglia stroke			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain stem ischaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	0 / 3581 (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 / 3581 (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 / 3581 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Cerebellar ischaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral haematoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Cerebral infarction				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral ischaemia				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	14 / 3581 (0.39%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 1			
Cerebrovascular disorder				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical myelopathy				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Cervical radiculopathy				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervicobrachial syndrome				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervicogenic headache				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Dementia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dementia Alzheimer's type				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic coma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Dizziness				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Embololic cerebral infarction				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	5 / 3581 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Facial paralysis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Facial paresis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic cerebral infarction				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic transformation stroke				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiplegia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic encephalopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotonia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Internal carotid artery kinking			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial aneurysm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Ischaemic cerebral infarction				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	13 / 3581 (0.36%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Lacunar infarction				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lumbosacral radiculopathy				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meralgia paraesthetica				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Motor dysfunction				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Multiple sclerosis relapse				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nerve compression				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nerve root compression				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuropathy peripheral				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Normal pressure hydrocephalus				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nystagmus				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paralysis recurrent laryngeal nerve				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paresis				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Post herpetic neuralgia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post-traumatic headache			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ruptured cerebral aneurysm			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Sciatica			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Somnolence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		



deaths causally related to treatment / all	0 / 0			
Stupor				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	9 / 3581 (0.25%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Tension headache				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	13 / 3581 (0.36%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Tremor				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Trigeminal neuralgia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular encephalopathy				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertebrobasilar insufficiency				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angle closure glaucoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blindness unilateral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences causally related to treatment / all	1 / 18		
deaths causally related to treatment / all	0 / 0		
Cystoid macular oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glaucoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lens disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Posterior capsule rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uveitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deafness unilateral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoacusis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniere's disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular ataxia			
subjects affected / exposed	0 / 3581 (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 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences causally related to treatment / all	1 / 10		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute abdomen			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Anal prolapse				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic gastritis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Coeliac disease				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	5 / 3581 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer haemorrhage				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspepsia				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femoral hernia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Fistula of small intestine				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Functional gastrointestinal disorder				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric polyps				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer perforation				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal angiodysplasia				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal hypomotility				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal necrosis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hernial eventration				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			



deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incarcerated inguinal hernia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incarcerated umbilical hernia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Intestinal perforation				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Irritable bowel syndrome				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestinal ulcer				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Mallory-Weiss syndrome				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mechanical ileus				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric artery thrombosis				
subjects affected / exposed	1 / 3581 (0.03%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic cyst rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic fistula			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Pancreatitis chronic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Peritoneal adhesions				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal prolapse				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Reflux gastritis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal haematoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Small intestinal perforation				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toothache				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Acute prerenal failure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis haemorrhagic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocalyx			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal infarct			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal injury			
subjects affected / exposed	0 / 3581 (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 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric perforation			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract inflammation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device dislocation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Dermatitis</b>				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
<b>Dermatitis allergic</b>				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
<b>Dermatitis exfoliative</b>				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
<b>Granuloma annulare</b>				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
<b>Ingrowing nail</b>				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Lichen sclerosus</b>				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Psoriasis</b>				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
<b>Rash</b>				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			



deaths causally related to treatment / all	0 / 0		
Rash macular			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin necrosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	0 / 3581 (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	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arthropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences causally related to treatment / all	0 / 6		

deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chondrocalcinosis pyrophosphate				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coccydynia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fracture pain				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemarthrosis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc compression				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Intervertebral disc degeneration				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Meniscal degeneration				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle haemorrhage				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteitis deformans				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	21 / 3581 (0.59%)			

occurrences causally related to treatment / all	1 / 25			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis of jaw				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pain in jaw				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psoriatic arthropathy				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scoliosis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			

deaths causally related to treatment / all	0 / 0		
Spinal column stenosis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Trigger finger			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Goitre			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences causally related to treatment / all	1 / 5		

deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Primary hyperaldosteronism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetic metabolic decompensation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		

deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Folate deficiency				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypochloraemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Hypoglycaemia				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hyponatraemic syndrome				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoosmolar state				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malnutrition				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mineral metabolism disorder				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Type 2 diabetes mellitus				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vitamin B12 deficiency				
subjects affected / exposed	1 / 3581 (0.03%)			



occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Amoebiasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amoebic colitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to	0 / 2		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial tracheitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	9 / 3581 (0.25%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis viral				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	11 / 3581 (0.31%)			
occurrences causally related to treatment / all	1 / 12			
deaths causally related to treatment / all	0 / 0			
Chikungunya virus infection				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chlamydial infection				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Chronic sinusitis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium colitis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis infected				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Empyema				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Encephalitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterobacter bacteraemia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye infection				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	6 / 3581 (0.17%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis bacterial				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis B				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis viral				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected dermal cyst				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of bronchiectasis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal gangrene				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Labyrinthitis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lyme disease				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphangitis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Medical device site joint infection				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis pneumococcal				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mycobacterium avium complex infection				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis chronic				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media acute				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perichondritis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perineal abscess				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis bacterial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis bacterial			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Phlebitis infective			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumococcal sepsis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	44 / 3581 (1.23%)		
occurrences causally related to treatment / all	2 / 51		
deaths causally related to treatment / all	0 / 2		
Pneumonia bacterial			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia cryptococcal			
subjects affected / exposed	1 / 3581 (0.03%)		



occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary sepsis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelocystitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Pyometra				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyonephrosis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Salmonellosis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	7 / 3581 (0.20%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Sinusitis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Streptococcal sepsis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tick-borne viral encephalitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ureteritis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	17 / 3581 (0.47%)			
occurrences causally related to treatment / all	1 / 21			
deaths causally related to treatment / all	0 / 1			
Urinary tract infection bacterial				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vaginitis bacterial				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vestibular neuronitis				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound abscess			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic thrombosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial occlusive disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Deep vein thrombosis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences causally related to	1 / 5		

treatment / all				
deaths causally related to treatment / all	1 / 1			
Dry gangrene				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	15 / 3581 (0.42%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	6 / 3581 (0.17%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Hypertensive emergency				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic venous thrombosis				
subjects affected / exposed	0 / 3581 (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	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Peripheral artery occlusion subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Shock haemorrhagic subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis superficial subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Varicose ulceration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular insufficiency			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Cardiac pacemaker replacement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract operation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hysterectomy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Knee arthroplasty			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteosynthesis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary resection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rehabilitation therapy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Scar excision			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acral lentiginous melanoma			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma gastric			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma of colon			



subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Adrenal adenoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Adrenal neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angiocentric lymphoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Basosquamous carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign breast neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign gastric neoplasm				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of adrenal gland				
subjects affected / exposed	0 / 3581 (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	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of spinal cord				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign ovarian tumour				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign pleural neoplasm				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign salivary gland neoplasm				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign soft tissue neoplasm				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Bladder cancer				
subjects affected / exposed	0 / 3581 (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 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm malignant				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer				
subjects affected / exposed	8 / 3581 (0.22%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 1			
Breast cancer female				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast cancer in situ				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer recurrent				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Breast cancer stage II				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer stage III				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervix carcinoma				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cervix carcinoma stage II				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Choroid melanoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon adenoma				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colon cancer metastatic				
subjects affected / exposed	1 / 3581 (0.03%)			

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Colon neoplasm				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colorectal adenocarcinoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colorectal cancer				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diffuse large B-cell lymphoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial adenocarcinoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibrous histiocytoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gallbladder cancer				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	1 / 2			

deaths causally related to treatment / all	0 / 0			
Glioblastoma multiforme				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Granular cell tumour				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cancer				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatocellular carcinoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Intraductal proliferative breast lesion				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraocular melanoma				
subjects affected / exposed	0 / 3581 (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	4 / 3581 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			

Large intestine benign neoplasm subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laryngeal squamous cell carcinoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Lentigo maligna subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma metastatic subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Lung neoplasm malignant subjects affected / exposed	13 / 3581 (0.36%)			
occurrences causally related to treatment / all	2 / 13			
deaths causally related to treatment / all	1 / 6			
Lymphoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of conjunctiva subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mantle cell lymphoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningioma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningioma benign			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Metastases to lymph nodes			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metastases to pleura			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0			
Metastatic malignant melanoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Nasopharyngeal cancer subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm of appendix subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma of the skin subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neurofibroma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal carcinoma subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma recurrent				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian adenoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Ovarian cancer metastatic				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paget's disease of nipple				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancoast's tumour				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Pancreatic neuroendocrine tumour				
subjects affected / exposed	0 / 3581 (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 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paranasal sinus benign neoplasm				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Phaeochromocytoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pituitary tumour benign				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plasma cell myeloma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pyogenic granuloma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal adenocarcinoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal cancer stage II				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectosigmoid cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal adenoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestine carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Squamous cell carcinoma of pharynx				
subjects affected / exposed	0 / 3581 (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	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the hypopharynx				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tracheal cancer				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic shock				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immobile			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Complication associated with device			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences causally related to	1 / 13		

treatment / all				
deaths causally related to treatment / all	1 / 13			
General physical health deterioration				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Medical device discomfort				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mucosal dryness				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Non-cardiac chest pain				
subjects affected / exposed	10 / 3581 (0.28%)			
occurrences causally related to treatment / all	1 / 10			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcoholism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bipolar I disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	3 / 3581 (0.08%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Personality change due to a general medical condition				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudodementia				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Psychotic disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schizophreniform disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient psychosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystocele			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Dysfunctional uterine bleeding			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Endometrial hyperplasia				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endometrial hypertrophy				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Female genital tract fistula				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Fibrocystic breast disease				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Pelvic haematoma				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic prolapse				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectocele				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urogenital prolapse				
subjects affected / exposed	0 / 3581 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Uterovaginal prolapse			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vaginal haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Alveolitis allergic				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	8 / 3581 (0.22%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Asthmatic crisis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchial hyperreactivity				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiectasis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Choking sensation				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	22 / 3581 (0.61%)			
occurrences causally related to treatment / all	1 / 24			
deaths causally related to treatment / all	0 / 1			
Dyspnoea exertional				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Pneumothorax				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	9 / 3581 (0.25%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 2			

Pulmonary mass			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Sinus polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord cyst			
subjects affected / exposed	0 / 3581 (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 / 3581 (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 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary dilatation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis sclerosing			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis obstructive			
subjects affected / exposed	0 / 3581 (0.00%)		



occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholestasis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic cyst				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic steatosis				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatocellular injury				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic hepatitis				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 1		
Jaundice cholestatic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Portal hypertension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Portal vein thrombosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sphincter of Oddi dysfunction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	12-Month Double-blind Period: Placebo	12-Month Double-blind Period: Romosozumab	36-Month Study Period: Placebo/Denosumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2823 / 3576 (78.94%)	2773 / 3581 (77.44%)	3130 / 3576 (87.53%)
Injury, poisoning and procedural complications			

Abdominal injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Accident at work			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Accidental exposure to product			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Anaemia postoperative			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	2	3	4
Animal bite			
subjects affected / exposed	10 / 3576 (0.28%)	4 / 3581 (0.11%)	18 / 3576 (0.50%)
occurrences (all)	11	4	20
Animal scratch			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Arthropod bite			
subjects affected / exposed	13 / 3576 (0.36%)	18 / 3581 (0.50%)	17 / 3576 (0.48%)
occurrences (all)	14	19	19
Arthropod sting			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Back injury			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	7 / 3576 (0.20%)
occurrences (all)	4	1	7
Bladder injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Bone fissure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0

Brain contusion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Breast injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Burns first degree			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Burns second degree			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	1	2	4
Buttock injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cartilage injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cataract operation complication			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Chemical burn of skin			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Chest crushing			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Chest injury			
subjects affected / exposed	15 / 3576 (0.42%)	5 / 3581 (0.14%)	29 / 3576 (0.81%)
occurrences (all)	16	5	30
Clavicle fracture			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	1	2	3
Concussion			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2

Conjunctival laceration subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Contusion subjects affected / exposed occurrences (all)	122 / 3576 (3.41%) 151	102 / 3581 (2.85%) 119	204 / 3576 (5.70%) 270
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Craniocerebral injury subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	3 / 3581 (0.08%) 3	4 / 3576 (0.11%) 4
Crushing injury of trunk subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Deafness traumatic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Epicondylitis subjects affected / exposed occurrences (all)	10 / 3576 (0.28%) 10	9 / 3581 (0.25%) 9	17 / 3576 (0.48%) 17
Eschar subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Excoriation subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	5 / 3581 (0.14%) 5	7 / 3576 (0.20%) 9
Exposure to communicable disease subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Eye burns subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Eye contusion subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	2 / 3581 (0.06%) 2	8 / 3576 (0.22%) 8

Eye injury			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Eye operation complication			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Eyelid injury			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Face injury			
subjects affected / exposed	10 / 3576 (0.28%)	5 / 3581 (0.14%)	13 / 3576 (0.36%)
occurrences (all)	10	6	14
Facial bones fracture			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	2	0	4
Fall			
subjects affected / exposed	319 / 3576 (8.92%)	255 / 3581 (7.12%)	539 / 3576 (15.07%)
occurrences (all)	378	321	801
Femoral neck fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Femur fracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Fibula fracture			
subjects affected / exposed	6 / 3576 (0.17%)	4 / 3581 (0.11%)	12 / 3576 (0.34%)
occurrences (all)	6	4	13
Foot fracture			
subjects affected / exposed	13 / 3576 (0.36%)	11 / 3581 (0.31%)	28 / 3576 (0.78%)
occurrences (all)	13	11	28
Foreign body			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Foreign body in eye			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Fracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Fractured ischium			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Gastrointestinal injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gingival injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Glaucoma traumatic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Graft complication			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hand fracture			
subjects affected / exposed	13 / 3576 (0.36%)	4 / 3581 (0.11%)	25 / 3576 (0.70%)
occurrences (all)	14	4	27
Head injury			
subjects affected / exposed	14 / 3576 (0.39%)	13 / 3581 (0.36%)	24 / 3576 (0.67%)
occurrences (all)	14	13	24
Heat exhaustion			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Heat illness			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Humerus fracture			
subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	9 / 3576 (0.25%)
occurrences (all)	2	5	9
Hypobarism			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0

Iliotibial band syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Injury			
subjects affected / exposed	18 / 3576 (0.50%)	14 / 3581 (0.39%)	22 / 3576 (0.62%)
occurrences (all)	18	15	23
Injury corneal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	8 / 3576 (0.22%)	5 / 3581 (0.14%)	12 / 3576 (0.34%)
occurrences (all)	9	8	13
Joint injury			
subjects affected / exposed	60 / 3576 (1.68%)	44 / 3581 (1.23%)	98 / 3576 (2.74%)
occurrences (all)	67	47	115
Laceration			
subjects affected / exposed	17 / 3576 (0.48%)	11 / 3581 (0.31%)	32 / 3576 (0.89%)
occurrences (all)	17	11	33
Ligament injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Ligament rupture			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Ligament sprain			
subjects affected / exposed	38 / 3576 (1.06%)	30 / 3581 (0.84%)	60 / 3576 (1.68%)
occurrences (all)	42	33	72
Limb injury			
subjects affected / exposed	54 / 3576 (1.51%)	65 / 3581 (1.82%)	97 / 3576 (2.71%)
occurrences (all)	59	71	104



Lip injury			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	0	2	2
Lumbar vertebral fracture			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Mallet finger			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Meniscus injury			
subjects affected / exposed	5 / 3576 (0.14%)	1 / 3581 (0.03%)	12 / 3576 (0.34%)
occurrences (all)	8	1	15
Mouth injury			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Multiple injuries			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Muscle injury			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Muscle rupture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Muscle strain			
subjects affected / exposed	13 / 3576 (0.36%)	12 / 3581 (0.34%)	23 / 3576 (0.64%)
occurrences (all)	13	12	24
Musculoskeletal injury			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nail injury			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	4	0
Nasal injury			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	5	3	6

Neck injury			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Nerve injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Overdose			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Patella fracture			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	3	1	4
Perineal injury			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Periorbital haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Periorbital haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Perirenal haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve injury			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Post procedural complication			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Post procedural contusion			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Post procedural fistula			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1

Post procedural haematoma subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Post procedural haemorrhage subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	2 / 3581 (0.06%) 2	2 / 3576 (0.06%) 2
Post procedural hypothyroidism subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Post procedural inflammation subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Post procedural swelling subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Post-traumatic neck syndrome subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Post-traumatic pain subjects affected / exposed occurrences (all)	13 / 3576 (0.36%) 14	9 / 3581 (0.25%) 10	17 / 3576 (0.48%) 18
Postoperative hernia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Postoperative ileus subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Postoperative wound complication subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	0 / 3576 (0.00%) 0
Postpericardiotomy syndrome subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Procedural complication subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Procedural dizziness			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Procedural haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Procedural headache			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Procedural pain			
subjects affected / exposed	27 / 3576 (0.76%)	22 / 3581 (0.61%)	40 / 3576 (1.12%)
occurrences (all)	27	23	43
Procedural pneumothorax			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pubis fracture			
subjects affected / exposed	4 / 3576 (0.11%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	4	0	4
Pulmonary contusion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Radiation associated pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Radiation proctitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Radius fracture			
subjects affected / exposed	25 / 3576 (0.70%)	22 / 3581 (0.61%)	52 / 3576 (1.45%)
occurrences (all)	25	22	53
Rib fracture			
subjects affected / exposed	12 / 3576 (0.34%)	3 / 3581 (0.08%)	21 / 3576 (0.59%)
occurrences (all)	12	3	22

Road traffic accident			
subjects affected / exposed	10 / 3576 (0.28%)	12 / 3581 (0.34%)	14 / 3576 (0.39%)
occurrences (all)	10	13	14
Scar			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	5 / 3576 (0.14%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	5	1	5
Seroma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Skeletal injury			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	3
Skin abrasion			
subjects affected / exposed	15 / 3576 (0.42%)	11 / 3581 (0.31%)	23 / 3576 (0.64%)
occurrences (all)	16	11	26
Skin injury			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	4	2	4
Skin wound			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Skull fracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Soft tissue injury			
subjects affected / exposed	37 / 3576 (1.03%)	28 / 3581 (0.78%)	47 / 3576 (1.31%)
occurrences (all)	39	35	53
Spinal column injury			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	2	2	5
Spinal compression fracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1

Spinal fracture			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	1	4
Splinter			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Stab wound			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sternal fracture			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Sternal injury			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Subdural haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Sunburn			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Suture related complication			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Synovial rupture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tendon injury			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3

Tendon rupture			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	4	4	7
Thermal burn			
subjects affected / exposed	11 / 3576 (0.31%)	9 / 3581 (0.25%)	23 / 3576 (0.64%)
occurrences (all)	11	9	24
Thoracic vertebral fracture			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Tibia fracture			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Tongue injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Tooth fracture			
subjects affected / exposed	28 / 3576 (0.78%)	31 / 3581 (0.87%)	54 / 3576 (1.51%)
occurrences (all)	29	34	62
Tooth injury			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences (all)	2	1	6
Toxicity to various agents			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Traumatic haematoma			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	5	3	5
Traumatic haemorrhage			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	5
Traumatic lung injury			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Traumatic ulcer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Ulna fracture subjects affected / exposed occurrences (all)	8 / 3576 (0.22%) 8	5 / 3581 (0.14%) 5	20 / 3576 (0.56%) 21
Ulnar nerve injury subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Vaccination complication subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Vascular injury subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	10 / 3576 (0.28%) 10	20 / 3581 (0.56%) 21	30 / 3576 (0.84%) 30
Wound secretion subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Investigations			
Abdominal bruit subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 7	4 / 3581 (0.11%) 4	16 / 3576 (0.45%) 16
Amylase increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Antinuclear antibody increased subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Aortic bruit subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)



occurrences (all)	0	1	0
Arterial bruit			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Arteriogram coronary abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 3576 (0.25%)	3 / 3581 (0.08%)	16 / 3576 (0.45%)
occurrences (all)	9	3	17
Aspiration bronchial			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Bacterial test			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Beta 2 microglobulin increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Blood bicarbonate decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Blood calcium increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Blood chloride decreased			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Blood folate decreased			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Blood glucose abnormal			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	1	3	1
Blood glucose increased			
subjects affected / exposed	4 / 3576 (0.11%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	4	0	6
Blood immunoglobulin G increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Blood iron decreased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Blood iron increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Blood parathyroid hormone increased			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Blood potassium decreased			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	2

Blood potassium increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	0 / 3576 (0.00%) 0
Blood pressure decreased subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Blood pressure increased subjects affected / exposed occurrences (all)	21 / 3576 (0.59%) 21	13 / 3581 (0.36%) 13	39 / 3576 (1.09%) 42
Blood pressure systolic increased subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Blood urea increased subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	5 / 3576 (0.14%) 5
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Body height abnormal subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Body height decreased subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	4 / 3581 (0.11%) 4	2 / 3576 (0.06%) 2
Body mass index increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Body temperature increased subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)

occurrences (all)	0	3	0
Bone density decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Brain scan abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Cardiac murmur			
subjects affected / exposed	9 / 3576 (0.25%)	2 / 3581 (0.06%)	16 / 3576 (0.45%)
occurrences (all)	9	2	16
Carotid bruit			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Carotid pulse abnormal			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Carotid pulse increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	8 / 3576 (0.22%)
occurrences (all)	3	1	9
Coagulation time prolonged			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Computerised tomogram head abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			

subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Creatinine renal clearance increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Ejection fraction decreased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram Q wave abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Electrocardiogram abnormal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Eosinophil count increased			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Faecal calprotectin increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	1	0	1
Glomerular filtration rate abnormal subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Glomerular filtration rate decreased subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Glycosylated haemoglobin increased subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Grip strength decreased subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Haemoglobin decreased subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Heart rate increased subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Heart rate irregular subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Helicobacter test positive subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	0	0	3
Hepatic enzyme abnormal subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hepatic enzyme increased subjects affected / exposed	5 / 3576 (0.14%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	5	1	5
Hepatitis A antibody positive subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hepatitis B surface antigen positive subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Hepatitis C virus test positive subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hepatobiliary scan abnormal subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Human epidermal growth factor receptor decreased subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Intraocular pressure increased subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Liver function test abnormal subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Liver function test increased subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Low density lipoprotein increased subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Lymphocyte morphology abnormal subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mammogram abnormal subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Monocyte count increased subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			

subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Neutrophil count increased			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Occult blood			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Occult blood positive			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Pancreatic enzymes increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Protein total increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pulmonary arterial pressure increased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Red blood cell sedimentation rate increased			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Reticulocyte count decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Rheumatoid factor positive			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1



Thyroid function test abnormal subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Transaminases increased subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	2 / 3581 (0.06%) 2	10 / 3576 (0.28%) 11
Tuberculin test positive subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Ultrasound liver abnormal subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Urinary system X-ray subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Urine output decreased subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Valsalva maneuver subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vitamin B12 increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	12 / 3576 (0.34%) 12	23 / 3581 (0.64%) 24	45 / 3576 (1.26%) 46
Weight increased subjects affected / exposed occurrences (all)	11 / 3576 (0.31%) 11	7 / 3581 (0.20%) 7	15 / 3576 (0.42%) 15
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 2	0 / 3576 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0

X-ray abnormal subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Cardiac disorders			
Acute myocardial infarction subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Angina pectoris subjects affected / exposed occurrences (all)	13 / 3576 (0.36%) 14	7 / 3581 (0.20%) 10	23 / 3576 (0.64%) 24
Angina unstable subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Aortic valve calcification subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Aortic valve disease subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Aortic valve incompetence subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 7	7 / 3581 (0.20%) 7	17 / 3576 (0.48%) 17
Aortic valve sclerosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Aortic valve stenosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	4 / 3576 (0.11%) 4
Arrhythmia subjects affected / exposed occurrences (all)	10 / 3576 (0.28%) 10	8 / 3581 (0.22%) 8	18 / 3576 (0.50%) 18
Arrhythmia supraventricular subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Arteriosclerosis coronary artery subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)

occurrences (all)	2	1	4
Atrial fibrillation			
subjects affected / exposed	12 / 3576 (0.34%)	13 / 3581 (0.36%)	34 / 3576 (0.95%)
occurrences (all)	15	18	38
Atrial flutter			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Atrial tachycardia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block first degree			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences (all)	3	1	6
Atrioventricular block second degree			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Bradycardia			
subjects affected / exposed	5 / 3576 (0.14%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	5	7	9
Bundle branch block left			
subjects affected / exposed	0 / 3576 (0.00%)	6 / 3581 (0.17%)	5 / 3576 (0.14%)
occurrences (all)	0	7	5
Bundle branch block right			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	10 / 3576 (0.28%)
occurrences (all)	3	2	10
Cardiac aneurysm			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Cardiac disorder			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Cardiac failure			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	11 / 3576 (0.31%)
occurrences (all)	7	7	12
Cardiac failure acute			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Cardiac failure chronic			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	3	4	9
Cardiac failure congestive			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	5	1	6
Cardiac hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Cardiac valve disease			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	2 / 3576 (0.06%)
occurrences (all)	2	4	2
Cardiac valve sclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Cardiac ventricular disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	5 / 3576 (0.14%)	6 / 3581 (0.17%)	7 / 3576 (0.20%)
occurrences (all)	5	6	7
Cardiomyopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cardiovascular disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Conduction disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Congestive cardiomyopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Coronary artery disease			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	14 / 3576 (0.39%)
occurrences (all)	7	7	15
Coronary artery insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Coronary artery occlusion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cyanosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Degenerative aortic valve disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Degenerative mitral valve disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	1	3	2
Dilatation atrial			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	1	3	1
Extrasystoles			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	4	2	7
Heart valve calcification			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Heart valve incompetence			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	7 / 3576 (0.20%)

occurrences (all)	3	3	7
Hypertensive cardiomegaly subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	3	2	3
Hypertensive cardiomyopathy subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	2	0	4
Hypertensive heart disease subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	2	4	4
Intracardiac thrombus subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Ischaemic cardiomyopathy subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	2
Left atrial dilatation subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	0	0	3
Left atrial enlargement subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Left atrial hypertrophy subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Left ventricular dysfunction subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	1	2	5
Left ventricular failure subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Left ventricular hypertrophy subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	2	4	4
Low cardiac output syndrome subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Mitral valve calcification			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mitral valve disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Mitral valve incompetence			
subjects affected / exposed	8 / 3576 (0.22%)	11 / 3581 (0.31%)	27 / 3576 (0.76%)
occurrences (all)	8	11	28
Mitral valve prolapse			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Mitral valve sclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Mitral valve stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Myocardial infarction			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Myocardial ischaemia			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	2	4	9
Palpitations			
subjects affected / exposed	27 / 3576 (0.76%)	24 / 3581 (0.67%)	35 / 3576 (0.98%)
occurrences (all)	27	24	36
Pericardial effusion			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Pericarditis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve incompetence			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)

occurrences (all)	0	1	1
Right atrial enlargement subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Right ventricular dysfunction subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Right ventricular enlargement subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Right ventricular hypertrophy subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Sinus arrhythmia subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Sinus bradycardia subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	5 / 3576 (0.14%)
occurrences (all)	2	5	5
Sinus node dysfunction subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Sinus tachycardia subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Supraventricular extrasystoles subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	4	4	9
Supraventricular tachycardia subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Systolic dysfunction subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tachyarrhythmia subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)



occurrences (all)	2	1	2
Tachycardia			
subjects affected / exposed	9 / 3576 (0.25%)	12 / 3581 (0.34%)	16 / 3576 (0.45%)
occurrences (all)	10	15	19
Tachycardia paroxysmal			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	3	2	3
Tricuspid valve incompetence			
subjects affected / exposed	4 / 3576 (0.11%)	9 / 3581 (0.25%)	20 / 3576 (0.56%)
occurrences (all)	4	9	20
Tricuspid valve stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Ventricular arrhythmia			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Ventricular extrasystoles			
subjects affected / exposed	4 / 3576 (0.11%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	4	7	9
Ventricular hypertrophy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Ventricular hypokinesia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Congenital, familial and genetic disorders			
Adenomatous polyposis coli			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Arteriovenous malformation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Bartter's syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0

Birth mark			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Congenital cystic kidney disease			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Cortical dysplasia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Dermoid cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dolichocolon			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Epidermolysis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Extrarenal pelvis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Fibrous dysplasia of bone			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gastrointestinal disorder congenital			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Intracranial lipoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Polycystic liver disease			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Porokeratosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Protein C deficiency			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Renal hypoplasia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Sacralisation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Spina bifida			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Spine malformation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Syringomyelia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Type IIa hyperlipidaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vertebral artery hypoplasia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	57 / 3576 (1.59%)	36 / 3581 (1.01%)	124 / 3576 (3.47%)
occurrences (all)	58	39	135
Anaemia folate deficiency			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Anaemia macrocytic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Anaemia megaloblastic			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bandaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Basophilia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Blood disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Bone marrow failure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Coagulopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Eosinophilia			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	5	3	6
Febrile neutropenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Granulocytosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic anaemia			

subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Hypergammaglobulinaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Hyperglobulinaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hypochromic anaemia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Immune thrombocytopenic purpura			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Increased tendency to bruise			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Iron deficiency anaemia			
subjects affected / exposed	14 / 3576 (0.39%)	12 / 3581 (0.34%)	16 / 3576 (0.45%)
occurrences (all)	14	12	16
Leukocytosis			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	10 / 3576 (0.28%)
occurrences (all)	3	3	10
Leukopenia			
subjects affected / exposed	13 / 3576 (0.36%)	14 / 3581 (0.39%)	21 / 3576 (0.59%)
occurrences (all)	13	16	22
Lymph node calcification			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Lymph node pain			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Lymphadenitis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Lymphadenopathy			

subjects affected / exposed	7 / 3576 (0.20%)	3 / 3581 (0.08%)	8 / 3576 (0.22%)
occurrences (all)	8	3	9
Lymphocytosis			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	1	3	1
Lymphopenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Nephrogenic anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	12 / 3576 (0.34%)	8 / 3581 (0.22%)	16 / 3576 (0.45%)
occurrences (all)	12	9	16
Neutrophilia			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pancytopenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Polycythaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Sideroblastic anaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Thrombocytopenia			

subjects affected / exposed occurrences (all)	6 / 3576 (0.17%) 6	4 / 3581 (0.11%) 4	15 / 3576 (0.42%) 17
Thrombocytosis subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	4 / 3581 (0.11%) 4	9 / 3576 (0.25%) 9
Nervous system disorders			
Acoustic neuritis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	2 / 3581 (0.06%) 2	1 / 3576 (0.03%) 1
Akathisia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Altered state of consciousness subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Amnesia subjects affected / exposed occurrences (all)	6 / 3576 (0.17%) 7	10 / 3581 (0.28%) 10	9 / 3576 (0.25%) 10
Aphonia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Arachnoid cyst subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Autonomic nervous system imbalance subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Balance disorder subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 7	10 / 3581 (0.28%) 11	8 / 3576 (0.22%) 9
Brain injury subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Burning feet syndrome subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Burning sensation			
subjects affected / exposed	6 / 3576 (0.17%)	8 / 3581 (0.22%)	9 / 3576 (0.25%)
occurrences (all)	6	8	9
Carotid arteriosclerosis			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	12 / 3576 (0.34%)
occurrences (all)	4	4	13
Carotid artery disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Carotid artery stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	1	0	7
Carpal tunnel syndrome			
subjects affected / exposed	13 / 3576 (0.36%)	9 / 3581 (0.25%)	27 / 3576 (0.76%)
occurrences (all)	16	9	33
Central nervous system lesion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cerebellar atrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cerebellar syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cerebral arteriosclerosis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Cerebral artery stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cerebral atrophy			
subjects affected / exposed	4 / 3576 (0.11%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	4	5	6
Cerebral calcification			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1



Cerebral disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cerebral haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Cerebral haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cerebral infarction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cerebral ischaemia			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	8 / 3576 (0.22%)
occurrences (all)	4	4	9
Cerebral microangiopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cerebrosclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cerebrovascular accident			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cerebrovascular disorder			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	11 / 3576 (0.31%)
occurrences (all)	8	4	12
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Cervical myelopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cervical radiculopathy			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	3	2	7

Cervicobrachial syndrome subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	2 / 3581 (0.06%) 2	7 / 3576 (0.20%) 7
Cognitive disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	4 / 3576 (0.11%) 4
Complex regional pain syndrome subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Cranial nerve disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Dementia subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	5 / 3576 (0.14%) 6
Dementia Alzheimer's type subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	3 / 3581 (0.08%) 3	9 / 3576 (0.25%) 9
Demyelination subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Diabetic neuropathy subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	3 / 3581 (0.08%) 3	7 / 3576 (0.20%) 8
Dizziness subjects affected / exposed occurrences (all)	158 / 3576 (4.42%) 181	154 / 3581 (4.30%) 174	216 / 3576 (6.04%) 259
Dizziness exertional subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Dizziness postural subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 4	3 / 3581 (0.08%) 3	3 / 3576 (0.08%) 4
Drooling subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0

Drug withdrawal headache subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Dysaesthesia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 4	2 / 3576 (0.06%) 2
Dysarthria subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Dysgeusia subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 8	5 / 3581 (0.14%) 6	10 / 3576 (0.28%) 11
Dyskinesia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Dysphonia psychogenic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Encephalopathy subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Epilepsy subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 2	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 4
Essential tremor subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Extrapyramidal disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Facial neuralgia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Facial paralysis subjects affected / exposed occurrences (all)	6 / 3576 (0.17%) 6	3 / 3581 (0.08%) 4	14 / 3576 (0.39%) 14

Generalised tonic-clonic seizure subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Haemorrhagic stroke subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Head discomfort subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	2 / 3576 (0.06%) 2
Headache subjects affected / exposed occurrences (all)	206 / 3576 (5.76%) 240	235 / 3581 (6.56%) 270	270 / 3576 (7.55%) 327
Hemianopia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Hemianopia heteronymous subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Hemiparesis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Hydrocephalus subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Hyperaesthesia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hypersomnia subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	0 / 3581 (0.00%) 0	4 / 3576 (0.11%) 4
Hypoaesthesia subjects affected / exposed occurrences (all)	20 / 3576 (0.56%) 22	36 / 3581 (1.01%) 43	31 / 3576 (0.87%) 34
Hyposmia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1

Hypotonia			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Intercostal neuralgia			
subjects affected / exposed	10 / 3576 (0.28%)	4 / 3581 (0.11%)	11 / 3576 (0.31%)
occurrences (all)	11	4	13
Intracranial aneurysm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	3
Ischaemic stroke			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	0	0	3
Lacunar infarction			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Lethargy			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	3	0	4
Leukoencephalomyelitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Leukoencephalopathy			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	1	1	4
Loss of consciousness			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	1	2	7
Lumbar radiculopathy			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	8 / 3576 (0.22%)
occurrences (all)	3	5	9
Lumbosacral radiculopathy			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Memory impairment			
subjects affected / exposed	11 / 3576 (0.31%)	10 / 3581 (0.28%)	27 / 3576 (0.76%)
occurrences (all)	11	10	27

Migraine			
subjects affected / exposed	12 / 3576 (0.34%)	12 / 3581 (0.34%)	17 / 3576 (0.48%)
occurrences (all)	16	13	24
Migraine with aura			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	0	2	2
Mononeuropathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Monoparesis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Morton's neuralgia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Movement disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Multiple sclerosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Multiple sclerosis relapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Myasthenia gravis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nerve compression			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Nerve root compression			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1

Nervous system disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	8 / 3576 (0.22%)	11 / 3581 (0.31%)	10 / 3576 (0.28%)
occurrences (all)	8	11	11
Neuritis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Neuropathy peripheral			
subjects affected / exposed	9 / 3576 (0.25%)	6 / 3581 (0.17%)	12 / 3576 (0.34%)
occurrences (all)	9	6	13
Noninfective encephalitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Occipital neuralgia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Optic neuritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Osmotic demyelination syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	61 / 3576 (1.71%)	72 / 3581 (2.01%)	86 / 3576 (2.40%)
occurrences (all)	65	83	96
Paraparesis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Parkinson's disease			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	4	4	9
Parkinsonism			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1

Parosmia			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	3	2	5
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Peripheral nerve palsy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Peripheral nerve paresis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Polyneuropathy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Poor quality sleep			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Post herpetic neuralgia			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	10 / 3576 (0.28%)
occurrences (all)	4	4	10
Post polio syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Post-traumatic epilepsy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Post-traumatic headache			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0



Precerebral arteriosclerosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Presyncope subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	2 / 3576 (0.06%) 2
Pseudoradicular syndrome subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Psychomotor hyperactivity subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Radicular pain subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 3	2 / 3576 (0.06%) 2
Radicular syndrome subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Radiculopathy subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	8 / 3581 (0.22%) 9	7 / 3576 (0.20%) 9
Restless legs syndrome subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	4 / 3581 (0.11%) 4	5 / 3576 (0.14%) 5
Sciatic nerve neuropathy subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Sciatica subjects affected / exposed occurrences (all)	42 / 3576 (1.17%) 43	44 / 3581 (1.23%) 50	87 / 3576 (2.43%) 100
Sedation subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Seizure subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1

Senile dementia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sinus headache			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	13 / 3576 (0.36%)	11 / 3581 (0.31%)	16 / 3576 (0.45%)
occurrences (all)	13	11	19
Speech disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Spinal cord disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Spinal meningeal cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	30 / 3576 (0.84%)	20 / 3581 (0.56%)	43 / 3576 (1.20%)
occurrences (all)	31	21	49
Tarsal tunnel syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	12 / 3576 (0.34%)	14 / 3581 (0.39%)	16 / 3576 (0.45%)
occurrences (all)	12	14	16
Tongue biting			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Transient ischaemic attack			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	1	3	5
Tremor			
subjects affected / exposed	9 / 3576 (0.25%)	12 / 3581 (0.34%)	14 / 3576 (0.39%)
occurrences (all)	10	13	15

Trigeminal nerve paresis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Trigeminal neuralgia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Trigeminal neuritis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Unresponsive to stimuli subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vlth nerve paralysis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vascular dementia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vascular encephalopathy subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vertebrobasilar insufficiency subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Vertigo CNS origin subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Visual field defect subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Vocal cord paralysis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
White matter lesion subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2

Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Amaurosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Amblyopia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Angle closure glaucoma			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	3	0	5
Arteriosclerotic retinopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Asthenopia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Astigmatism			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Blepharitis			
subjects affected / exposed	6 / 3576 (0.17%)	6 / 3581 (0.17%)	10 / 3576 (0.28%)
occurrences (all)	7	6	11
Blepharitis allergic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Blepharochalasis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Blindness transient			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Blindness unilateral subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	49 / 3576 (1.37%) 60	66 / 3581 (1.84%) 84	127 / 3576 (3.55%) 151
Cataract diabetic subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Cataract nuclear subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Chalazion subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	5 / 3576 (0.14%) 5
Chorioretinopathy subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	10 / 3581 (0.28%) 10	9 / 3576 (0.25%) 9
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 2	1 / 3576 (0.03%) 1
Conjunctival irritation subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Conjunctival ulcer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Conjunctivitis allergic subjects affected / exposed occurrences (all)	17 / 3576 (0.48%) 17	15 / 3581 (0.42%) 15	23 / 3576 (0.64%) 23
Conjunctivochalasis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Corneal degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Corneal leukoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dacryostenosis acquired			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	2 / 3576 (0.06%)
occurrences (all)	1	4	2
Diabetic retinopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	0	1	3
Diplopia			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	4
Dry age-related macular degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	10 / 3576 (0.28%)	15 / 3581 (0.42%)	20 / 3576 (0.56%)
occurrences (all)	11	15	21
Ectropion			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Entropion			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Erythema of eyelid			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Exfoliation glaucoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Exophthalmos			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0

Eye allergy			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	3	1	5
Eye discharge			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Eye disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Eye haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	1	3	3
Eye inflammation			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	2	3	3
Eye irritation			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	1	1	4
Eye movement disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	5 / 3576 (0.14%)	7 / 3581 (0.20%)	8 / 3576 (0.22%)
occurrences (all)	5	9	8
Eye pruritus			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	3	5	4
Eye swelling			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Eyelid disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Eyelid haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1

Eyelid oedema			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	3 / 3576 (0.08%)
occurrences (all)	2	4	3
Eyelid ptosis			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	2	2	8
Eyelid rash			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	3
Foreign body sensation in eyes			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Glaucoma			
subjects affected / exposed	8 / 3576 (0.22%)	18 / 3581 (0.50%)	29 / 3576 (0.81%)
occurrences (all)	8	18	29
Hypermetropia			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	3	0	3
Iritis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Keratitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Keratopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lacrimal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	7	7	9



Lenticular opacities			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	6 / 3576 (0.17%)	8 / 3581 (0.22%)	13 / 3576 (0.36%)
occurrences (all)	7	8	14
Macular fibrosis			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	3	1	4
Macular hole			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Macular oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Maculopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Meibomian gland dysfunction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Mydriasis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Ocular discomfort			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	3	5	6
Open angle glaucoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Photopsia			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	3	1	4
Posterior capsule opacification			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Presbyopia			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Pterygium			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Refraction disorder			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	1 / 3576 (0.03%)
occurrences (all)	1	4	1
Retinal degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Retinal detachment			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Retinal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Retinal dystrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Retinal haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Retinal tear			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Retinal vascular disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Retinal vascular thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Retinal vein occlusion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Retinal vein thrombosis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Retinopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Retinopathy hypertensive			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Scleral haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Strabismus			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Sudden visual loss			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Trichiasis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Uveitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	14 / 3576 (0.39%)	8 / 3581 (0.22%)	19 / 3576 (0.53%)
occurrences (all)	14	8	20
Visual acuity reduced			
subjects affected / exposed	9 / 3576 (0.25%)	8 / 3581 (0.22%)	14 / 3576 (0.39%)

occurrences (all)	9	8	14
Visual acuity reduced transiently subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Visual impairment subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	11 / 3576 (0.31%)
occurrences (all)	8	4	12
Vitreous degeneration subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vitreous detachment subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	1	3	4
Vitreous disorder subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Vitreous floaters subjects affected / exposed	5 / 3576 (0.14%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences (all)	5	4	7
Vitreous haemorrhage subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Xerophthalmia subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Ear and labyrinth disorders			
Acute vestibular syndrome subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Auditory disorder subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cerumen impaction subjects affected / exposed	10 / 3576 (0.28%)	10 / 3581 (0.28%)	17 / 3576 (0.48%)
occurrences (all)	10	10	17
Conductive deafness			

subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Deafness			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	3	1	4
Deafness bilateral			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences (all)	4	4	7
Deafness neurosensory			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	3	3	4
Deafness unilateral			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	2	3	3
Dysacusis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Ear congestion			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	3	2	3
Ear discomfort			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Ear disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Ear pain			
subjects affected / exposed	15 / 3576 (0.42%)	14 / 3581 (0.39%)	24 / 3576 (0.67%)
occurrences (all)	15	15	27
Ear pruritus			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	3	2	3
Excessive cerumen production			
subjects affected / exposed	3 / 3576 (0.08%)	8 / 3581 (0.22%)	6 / 3576 (0.17%)
occurrences (all)	3	8	6
External ear disorder			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Hypoacusis			
subjects affected / exposed	16 / 3576 (0.45%)	12 / 3581 (0.34%)	21 / 3576 (0.59%)
occurrences (all)	16	12	21
Inner ear disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Meniere's disease			
subjects affected / exposed	6 / 3576 (0.17%)	2 / 3581 (0.06%)	9 / 3576 (0.25%)
occurrences (all)	6	2	9
Middle ear effusion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Middle ear inflammation			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Mixed deafness			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Motion sickness			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	4	1
Neurosensory hypoacusis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Otorrhoea			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Otosclerosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	3
Presbycusis			

subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Sudden hearing loss subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Tinnitus subjects affected / exposed occurrences (all)	29 / 3576 (0.81%) 30	28 / 3581 (0.78%) 28	42 / 3576 (1.17%) 43
Tympanic membrane disorder subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Tympanic membrane perforation subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	4 / 3581 (0.11%) 4	6 / 3576 (0.17%) 6
Tympanosclerosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vertigo subjects affected / exposed occurrences (all)	80 / 3576 (2.24%) 92	62 / 3581 (1.73%) 69	117 / 3576 (3.27%) 140
Vertigo labyrinthine subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Vertigo positional subjects affected / exposed occurrences (all)	8 / 3576 (0.22%) 10	6 / 3581 (0.17%) 6	15 / 3576 (0.42%) 17
Vestibular ataxia subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	4 / 3576 (0.11%) 4
Vestibular disorder subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Gastrointestinal disorders Abdominal adhesions subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Abdominal discomfort subjects affected / exposed occurrences (all)	11 / 3576 (0.31%) 12	5 / 3581 (0.14%) 6	16 / 3576 (0.45%) 18
Abdominal distension subjects affected / exposed occurrences (all)	28 / 3576 (0.78%) 32	27 / 3581 (0.75%) 29	36 / 3576 (1.01%) 43
Abdominal hernia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 3	2 / 3576 (0.06%) 2
Abdominal incarcerated hernia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Abdominal mass subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Abdominal pain subjects affected / exposed occurrences (all)	75 / 3576 (2.10%) 82	60 / 3581 (1.68%) 66	114 / 3576 (3.19%) 127
Abdominal pain lower subjects affected / exposed occurrences (all)	15 / 3576 (0.42%) 16	7 / 3581 (0.20%) 7	21 / 3576 (0.59%) 22
Abdominal pain upper subjects affected / exposed occurrences (all)	96 / 3576 (2.68%) 103	88 / 3581 (2.46%) 95	124 / 3576 (3.47%) 137
Abdominal tenderness subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Abnormal faeces subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	2 / 3581 (0.06%) 2	1 / 3576 (0.03%) 1
Acid peptic disease subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Amalgam tattoo subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0



Anal fissure			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Anal fistula			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Anal incontinence			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	2	0	6
Anal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Anal pruritus			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences (all)	4	1	7
Anorectal discomfort			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Anorectal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Anorectal varices			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	4 / 3576 (0.11%)	6 / 3581 (0.17%)	6 / 3576 (0.17%)
occurrences (all)	4	7	6
Ascites			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Barrett's oesophagus			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2

Bowel movement irregularity subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Breath odour subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Change of bowel habit subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Cheilitis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Chronic gastritis subjects affected / exposed occurrences (all)	14 / 3576 (0.39%) 14	21 / 3581 (0.59%) 21	33 / 3576 (0.92%) 34
Coeliac disease subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Colitis subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	1 / 3581 (0.03%) 1	8 / 3576 (0.22%) 9
Colitis ischaemic subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Colitis microscopic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Colitis psychogenic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Colitis ulcerative subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Colon dysplasia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1

Constipation			
subjects affected / exposed	162 / 3576 (4.53%)	138 / 3581 (3.85%)	210 / 3576 (5.87%)
occurrences (all)	173	150	232
Crohn's disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	50 / 3576 (1.40%)	63 / 3581 (1.76%)	99 / 3576 (2.77%)
occurrences (all)	53	72	114
Dental cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dental necrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Diaphragmatic hernia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	133 / 3576 (3.72%)	111 / 3581 (3.10%)	191 / 3576 (5.34%)
occurrences (all)	150	130	229
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Diverticulum			
subjects affected / exposed	11 / 3576 (0.31%)	11 / 3581 (0.31%)	19 / 3576 (0.53%)
occurrences (all)	11	12	19
Diverticulum intestinal			
subjects affected / exposed	13 / 3576 (0.36%)	10 / 3581 (0.28%)	20 / 3576 (0.56%)
occurrences (all)	13	11	20
Diverticulum oesophageal			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dry mouth			
subjects affected / exposed	14 / 3576 (0.39%)	22 / 3581 (0.61%)	20 / 3576 (0.56%)
occurrences (all)	14	23	21

Duodenal polyp subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Duodenal ulcer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Duodenitis subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	3 / 3581 (0.08%) 3	2 / 3576 (0.06%) 2
Duodenogastric reflux subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Dyspepsia subjects affected / exposed occurrences (all)	59 / 3576 (1.65%) 65	70 / 3581 (1.95%) 79	98 / 3576 (2.74%) 107
Dysphagia subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	3 / 3581 (0.08%) 4	7 / 3576 (0.20%) 9
Enamel anomaly subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Enterocolitis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Epigastric discomfort subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Erosive duodenitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	4 / 3576 (0.11%) 4
Erosive oesophagitis subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	2 / 3581 (0.06%) 2	3 / 3576 (0.08%) 3

Eructation			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Faeces discoloured			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Faeces hard			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Faeces pale			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Femoral hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	14 / 3576 (0.39%)	14 / 3581 (0.39%)	19 / 3576 (0.53%)
occurrences (all)	15	14	21
Food poisoning			
subjects affected / exposed	10 / 3576 (0.28%)	10 / 3581 (0.28%)	14 / 3576 (0.39%)
occurrences (all)	12	11	16
Frequent bowel movements			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Gastric disorder			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	5 / 3576 (0.14%)
occurrences (all)	1	4	5
Gastric mucosa erythema			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2

Gastric mucosal hypertrophy subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Gastric polyps subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	7 / 3581 (0.20%) 7	13 / 3576 (0.36%) 15
Gastric ulcer subjects affected / exposed occurrences (all)	9 / 3576 (0.25%) 9	1 / 3581 (0.03%) 1	16 / 3576 (0.45%) 16
Gastric xanthoma subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Gastritis subjects affected / exposed occurrences (all)	102 / 3576 (2.85%) 114	97 / 3581 (2.71%) 111	166 / 3576 (4.64%) 195
Gastritis erosive subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 7	10 / 3581 (0.28%) 10	15 / 3576 (0.42%) 15
Gastritis haemorrhagic subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Gastroduodenal ulcer subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Gastroduodenitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 2	3 / 3576 (0.08%) 3
Gastrointestinal angiodysplasia haemorrhagic subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Gastrointestinal disorder subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	3 / 3576 (0.08%) 3
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 3	2 / 3576 (0.06%) 2

Gastrointestinal inflammation subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Gastrointestinal mucosal disorder subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Gastrointestinal necrosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Gastrointestinal pain subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	2 / 3581 (0.06%) 2	3 / 3576 (0.08%) 3
Gastrointestinal sounds abnormal subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	0 / 3576 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	40 / 3576 (1.12%) 43	40 / 3581 (1.12%) 44	80 / 3576 (2.24%) 86
Gastrooesophageal sphincter insufficiency subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Gingival bleeding subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	4 / 3581 (0.11%) 5	3 / 3576 (0.08%) 3
Gingival disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 2	4 / 3576 (0.11%) 4
Gingival erosion subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Gingival erythema subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Gingival hypertrophy subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	7 / 3576 (0.20%)	9 / 3581 (0.25%)	7 / 3576 (0.20%)
occurrences (all)	7	9	7
Gingival recession			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Gingival swelling			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	1	3	3
Gingival ulceration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Glossitis			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	1	3	3
Glossodynia			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Haematemesis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Haematochezia			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	4	4	5
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Haemorrhoids			
subjects affected / exposed	30 / 3576 (0.84%)	23 / 3581 (0.64%)	51 / 3576 (1.43%)
occurrences (all)	30	23	52
Hiatus hernia			
subjects affected / exposed	20 / 3576 (0.56%)	14 / 3581 (0.39%)	41 / 3576 (1.15%)



occurrences (all)	20	14	41
Hyperchlorhydria			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	3	2	3
Ileal ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Impaired gastric emptying			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Inflammatory bowel disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	8 / 3576 (0.22%)
occurrences (all)	2	1	8
Intestinal haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Intestinal metaplasia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	0	0	3
Intestinal obstruction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Intestinal polyp			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Intra-abdominal haematoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Intussusception			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	26 / 3576 (0.73%)	27 / 3581 (0.75%)	47 / 3576 (1.31%)
occurrences (all)	28	28	52
Large intestinal stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Large intestinal ulcer			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Large intestine polyp			
subjects affected / exposed	10 / 3576 (0.28%)	9 / 3581 (0.25%)	18 / 3576 (0.50%)
occurrences (all)	10	9	18
Leukoplakia oral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Lip haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Lip swelling			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Lip ulceration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	11 / 3576 (0.31%)	17 / 3581 (0.47%)	21 / 3576 (0.59%)
occurrences (all)	12	18	23
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Lumbar hernia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Megacolon			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Mouth cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Mouth swelling			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	3 / 3576 (0.08%)
occurrences (all)	2	5	3
Mucous stools			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	57 / 3576 (1.59%)	52 / 3581 (1.45%)	68 / 3576 (1.90%)
occurrences (all)	61	54	74
Noninfective gingivitis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Odynophagia			
subjects affected / exposed	7 / 3576 (0.20%)	8 / 3581 (0.22%)	7 / 3576 (0.20%)
occurrences (all)	8	8	8
Oesophageal achalasia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Oesophageal disorder			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Oesophageal motility disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	8 / 3576 (0.22%)
occurrences (all)	3	5	8
Oral cavity fistula			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Oral contusion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Oral disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Oral lichen planus			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Oral mucosa erosion			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Oral mucosal blistering			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	6	0	7
Pancreatic cyst			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	1	2	4
Pancreatic disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)

occurrences (all)	1	0	2
Pancreatic duct dilatation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pancreatic fistula			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pancreatic pseudocyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Pancreatic steatosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Pancreatitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Pancreatitis acute			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pancreatitis chronic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Parotid gland enlargement			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Peptic ulcer			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	3	4
Periodontal disease			
subjects affected / exposed	6 / 3576 (0.17%)	5 / 3581 (0.14%)	10 / 3576 (0.28%)
occurrences (all)	6	5	11
Periodontal inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Peritoneal lesion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	3	0	5
Proctitis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Rectal haemorrhage			
subjects affected / exposed	5 / 3576 (0.14%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	5	2	7
Rectal polyp			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Rectal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Reflux gastritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Regurgitation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Salivary duct obstruction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Salivary gland enlargement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Salivary hypersecretion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Sciatic hernia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Sensitivity of teeth			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Stomatitis			
subjects affected / exposed	11 / 3576 (0.31%)	8 / 3581 (0.22%)	15 / 3576 (0.42%)
occurrences (all)	11	10	17
Submaxillary gland enlargement			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Swollen tongue			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Tongue blistering			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Tongue disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tongue haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Tongue ulceration			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Tooth deposit			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Tooth discolouration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Tooth disorder			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	9 / 3576 (0.25%)
occurrences (all)	3	4	9
Tooth loss			
subjects affected / exposed	27 / 3576 (0.76%)	26 / 3581 (0.73%)	55 / 3576 (1.54%)
occurrences (all)	29	27	62
Toothache			
subjects affected / exposed	33 / 3576 (0.92%)	30 / 3581 (0.84%)	48 / 3576 (1.34%)
occurrences (all)	36	33	52
Umbilical hernia			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	3	2	6
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Varices oesophageal			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Vomiting			
subjects affected / exposed	49 / 3576 (1.37%)	49 / 3581 (1.37%)	61 / 3576 (1.71%)
occurrences (all)	52	52	68
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Azotaemia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Bladder disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bladder diverticulum			



subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bladder dysfunction			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Bladder pain			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bladder prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	0 / 3576 (0.00%)
occurrences (all)	0	4	0
Bladder spasm			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Calculus bladder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Calculus urinary			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	5
Choluria			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Chromaturia			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Chronic kidney disease			
subjects affected / exposed	13 / 3576 (0.36%)	19 / 3581 (0.53%)	30 / 3576 (0.84%)
occurrences (all)	13	20	31
Cystitis haemorrhagic			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Cystitis interstitial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cystitis noninfective			

subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	3	1	4
Diabetic nephropathy			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	2	3	4
Dysuria			
subjects affected / exposed	10 / 3576 (0.28%)	16 / 3581 (0.45%)	23 / 3576 (0.64%)
occurrences (all)	10	17	24
Haematuria			
subjects affected / exposed	5 / 3576 (0.14%)	7 / 3581 (0.20%)	11 / 3576 (0.31%)
occurrences (all)	5	8	13
Hydrocalyx			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hydronephrosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hypercalciuria			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hypertensive nephropathy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Hypertonic bladder			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	3	5	7
Incontinence			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Kidney enlargement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Kidney fibrosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Leukocyturia			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Microalbuminuria			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Micturition disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Micturition urgency			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Nephrocalcinosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nephrolithiasis			
subjects affected / exposed	15 / 3576 (0.42%)	17 / 3581 (0.47%)	30 / 3576 (0.84%)
occurrences (all)	15	17	31
Nephropathy			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	3	0	3
Nephrosclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Neurogenic bladder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nocturia			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	3	3	3
Pollakiuria			
subjects affected / exposed	9 / 3576 (0.25%)	6 / 3581 (0.17%)	17 / 3576 (0.48%)
occurrences (all)	9	8	17
Polyuria			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	4	2	5
Proteinuria			

subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	4	1	6
Pyelocaliectasis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Renal artery stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Renal atrophy			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Renal colic			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	3	2	4
Renal cyst			
subjects affected / exposed	12 / 3576 (0.34%)	23 / 3581 (0.64%)	39 / 3576 (1.09%)
occurrences (all)	12	24	41
Renal disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Renal failure			
subjects affected / exposed	5 / 3576 (0.14%)	8 / 3581 (0.22%)	16 / 3576 (0.45%)
occurrences (all)	6	8	18
Renal impairment			
subjects affected / exposed	14 / 3576 (0.39%)	9 / 3581 (0.25%)	23 / 3576 (0.64%)
occurrences (all)	14	9	23
Renal lipomatosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Renal mass			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Renal pain			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	2	2	2
Stress urinary incontinence			

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	0	1	4
Ureteric dilatation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Ureteric stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Ureterolithiasis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Urethral caruncle			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Urethral pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Urethral stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Urethral syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Urge incontinence			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Urinary hesitation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Urinary incontinence			
subjects affected / exposed	14 / 3576 (0.39%)	15 / 3581 (0.42%)	28 / 3576 (0.78%)
occurrences (all)	14	16	28
Urinary retention			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	3
Urinary tract disorder			

subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Urinary tract inflammation subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Urine flow decreased subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Urine odour abnormal subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Urogenital haemorrhage subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Product issues			
Device breakage subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 6	5 / 3581 (0.14%) 5	5 / 3576 (0.14%) 6
Device dislocation subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Device extrusion subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Device failure subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	6 / 3581 (0.17%) 7	3 / 3576 (0.08%) 3
Device loosening subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Device malfunction subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)

occurrences (all)	0	1	1
Actinic keratosis			
subjects affected / exposed	6 / 3576 (0.17%)	6 / 3581 (0.17%)	11 / 3576 (0.31%)
occurrences (all)	6	6	11
Alopecia			
subjects affected / exposed	20 / 3576 (0.56%)	24 / 3581 (0.67%)	24 / 3576 (0.67%)
occurrences (all)	20	24	25
Alopecia areata			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Angiodermatitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Angioedema			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	6	0	6
Asteatosis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	3
Blister			
subjects affected / exposed	5 / 3576 (0.14%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences (all)	6	1	7
Blister rupture			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Chronic pigmented purpura			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cutis laxa			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Dandruff			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Decubitus ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)

occurrences (all)	0	1	1
Dermal cyst			
subjects affected / exposed	1 / 3576 (0.03%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	1	5	7
Dermatitis			
subjects affected / exposed	30 / 3576 (0.84%)	14 / 3581 (0.39%)	47 / 3576 (1.31%)
occurrences (all)	33	15	53
Dermatitis acneiform			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	31 / 3576 (0.87%)	24 / 3581 (0.67%)	51 / 3576 (1.43%)
occurrences (all)	32	27	56
Dermatitis atopic			
subjects affected / exposed	5 / 3576 (0.14%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	5	0	6
Dermatitis bullous			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dermatitis contact			
subjects affected / exposed	15 / 3576 (0.42%)	10 / 3581 (0.28%)	22 / 3576 (0.62%)
occurrences (all)	17	10	26
Diabetic dermopathy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Diabetic foot			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Drug eruption			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	3	4	4
Dry skin			
subjects affected / exposed	10 / 3576 (0.28%)	9 / 3581 (0.25%)	14 / 3576 (0.39%)
occurrences (all)	10	9	14
Dyshidrotic eczema			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)



occurrences (all)	2	1	2
Ecchymosis			
subjects affected / exposed	28 / 3576 (0.78%)	26 / 3581 (0.73%)	42 / 3576 (1.17%)
occurrences (all)	32	28	50
Eczema			
subjects affected / exposed	27 / 3576 (0.76%)	23 / 3581 (0.64%)	51 / 3576 (1.43%)
occurrences (all)	29	24	55
Eczema asteatotic			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	5	1	8
Erythema			
subjects affected / exposed	13 / 3576 (0.36%)	20 / 3581 (0.56%)	19 / 3576 (0.53%)
occurrences (all)	14	30	21
Erythema multiforme			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Exfoliative rash			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Generalised erythema			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Granuloma annulare			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	4	0
Haemorrhage subcutaneous			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	1	4
Hand dermatitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Hirsutism			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	12 / 3576 (0.34%)	4 / 3581 (0.11%)	13 / 3576 (0.36%)

occurrences (all)	12	4	13
Hyperkeratosis			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	8 / 3576 (0.22%)
occurrences (all)	7	7	8
Hypertrophic scar			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Idiopathic urticaria			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	4	4	9
Intertrigo			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	0	2	3
Leukoplakia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Lichen sclerosus			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Lipohypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Macule			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	3	3	7
Mechanical urticaria			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)

occurrences (all)	1	3	3
Nail bed disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Nail bed inflammation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nail discolouration			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Nail disorder			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Nail hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Nail psoriasis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nail ridging			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	0 / 3576 (0.00%)
occurrences (all)	0	4	0
Neurodermatitis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Night sweats			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	2	4	4
Onychoclasia			
subjects affected / exposed	15 / 3576 (0.42%)	4 / 3581 (0.11%)	15 / 3576 (0.42%)
occurrences (all)	15	4	15
Onycholysis			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Onychomadesis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)

occurrences (all)	2	1	2
Onychomalacia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Palmoplantar keratoderma			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Panniculitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Papule			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	5	3	5
Peau d'orange			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	2	0	4
Petechiae			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Photosensitivity reaction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Pigmentation disorder			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Pityriasis rosea			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Pruritus			
subjects affected / exposed	47 / 3576 (1.31%)	45 / 3581 (1.26%)	66 / 3576 (1.85%)
occurrences (all)	49	53	71
Pruritus allergic			
subjects affected / exposed	5 / 3576 (0.14%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)

occurrences (all)	7	1	8
Pruritus generalised			
subjects affected / exposed	20 / 3576 (0.56%)	17 / 3581 (0.47%)	27 / 3576 (0.76%)
occurrences (all)	22	20	31
Psoriasis			
subjects affected / exposed	6 / 3576 (0.17%)	6 / 3581 (0.17%)	12 / 3576 (0.34%)
occurrences (all)	8	7	15
Purpura			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	31 / 3576 (0.87%)	38 / 3581 (1.06%)	53 / 3576 (1.48%)
occurrences (all)	37	44	61
Rash erythematous			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	0 / 3576 (0.00%)
occurrences (all)	0	5	0
Rash generalised			
subjects affected / exposed	0 / 3576 (0.00%)	5 / 3581 (0.14%)	0 / 3576 (0.00%)
occurrences (all)	0	5	0
Rash macular			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Rash maculo-papular			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Rash papular			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Rash pruritic			
subjects affected / exposed	15 / 3576 (0.42%)	11 / 3581 (0.31%)	18 / 3576 (0.50%)
occurrences (all)	16	12	22
Rosacea			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Scab			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	3 / 3576 (0.08%)	7 / 3581 (0.20%)	5 / 3576 (0.14%)
occurrences (all)	3	8	5
Skin atrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin burning sensation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Skin discolouration			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Skin disorder			
subjects affected / exposed	5 / 3576 (0.14%)	7 / 3581 (0.20%)	6 / 3576 (0.17%)
occurrences (all)	5	7	7
Skin erosion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	4	1	5
Skin fissures			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Skin haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	3	0	4
Skin hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	2	0
Skin induration			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	3	1	3
Skin lesion			
subjects affected / exposed	20 / 3576 (0.56%)	12 / 3581 (0.34%)	27 / 3576 (0.76%)
occurrences (all)	20	13	28
Skin mass			
subjects affected / exposed	4 / 3576 (0.11%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	4	0	5
Skin plaque			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin swelling			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	7	4	10
Skin ulcer haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin warm			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Solar dermatitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Solar lentigo			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Stasis dermatitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)

occurrences (all)	1	0	2
Subcutaneous emphysema			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sweat gland disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Telangiectasia			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Trichorrhexis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	22 / 3576 (0.62%)	18 / 3581 (0.50%)	29 / 3576 (0.81%)
occurrences (all)	23	22	31
Urticaria chronic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Vascular purpura			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Vascular skin disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Vitiligo			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Xeroderma			
subjects affected / exposed	5 / 3576 (0.14%)	7 / 3581 (0.20%)	12 / 3576 (0.34%)



occurrences (all)	5	8	12
Musculoskeletal and connective tissue disorders			
Ankle deformity			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	434 / 3576 (12.14%)	468 / 3581 (13.07%)	663 / 3576 (18.54%)
occurrences (all)	532	594	882
Arthritis			
subjects affected / exposed	12 / 3576 (0.34%)	19 / 3581 (0.53%)	18 / 3576 (0.50%)
occurrences (all)	12	20	21
Arthritis reactive			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Arthropathy			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	1	1	5
Back pain			
subjects affected / exposed	380 / 3576 (10.63%)	373 / 3581 (10.42%)	573 / 3576 (16.02%)
occurrences (all)	431	434	707
Bone atrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Bone cyst			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Bone deformity			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Bone disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Bone infarction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	1	0	1
Bone loss			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	0	2	2
Bone pain			
subjects affected / exposed	47 / 3576 (1.31%)	55 / 3581 (1.54%)	62 / 3576 (1.73%)
occurrences (all)	60	67	78
Bursitis			
subjects affected / exposed	13 / 3576 (0.36%)	19 / 3581 (0.53%)	21 / 3576 (0.59%)
occurrences (all)	13	20	22
Cervical spinal stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Chondritis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Chondrocalcinosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Chondrolysis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Chondromalacia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Chondropathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Coccydynia			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	4	2	6
Costochondritis			
subjects affected / exposed	14 / 3576 (0.39%)	8 / 3581 (0.22%)	25 / 3576 (0.70%)

occurrences (all)	14	9	26
Crystal arthropathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Deformity thorax			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Dupuytren's contracture			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Enthesopathy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	0	2	2
Exostosis			
subjects affected / exposed	12 / 3576 (0.34%)	6 / 3581 (0.17%)	26 / 3576 (0.73%)
occurrences (all)	14	7	28
Extremity contracture			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Facial asymmetry			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Fasciitis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Fibromyalgia			
subjects affected / exposed	10 / 3576 (0.28%)	5 / 3581 (0.14%)	11 / 3576 (0.31%)
occurrences (all)	10	5	11
Finger deformity			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Fistula			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	4 / 3576 (0.11%)	12 / 3581 (0.34%)	9 / 3576 (0.25%)

occurrences (all)	4	12	9
Foot deformity			
subjects affected / exposed	8 / 3576 (0.22%)	9 / 3581 (0.25%)	15 / 3576 (0.42%)
occurrences (all)	9	10	17
Fracture delayed union			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	5 / 3576 (0.14%)	4 / 3581 (0.11%)	5 / 3576 (0.14%)
occurrences (all)	5	5	5
Gouty arthritis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Groin pain			
subjects affected / exposed	9 / 3576 (0.25%)	14 / 3581 (0.39%)	17 / 3576 (0.48%)
occurrences (all)	11	14	20
Interspinous osteoarthritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc compression			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Intervertebral disc degeneration			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	1	2	7
Intervertebral disc disorder			
subjects affected / exposed	12 / 3576 (0.34%)	16 / 3581 (0.45%)	22 / 3576 (0.62%)
occurrences (all)	13	16	26
Intervertebral disc displacement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Intervertebral disc protrusion			
subjects affected / exposed	12 / 3576 (0.34%)	8 / 3581 (0.22%)	24 / 3576 (0.67%)
occurrences (all)	14	8	29
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)

occurrences (all)	1	1	1
Jaw cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Joint contracture			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	1	2	4
Joint crepitation			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	3	1	4
Joint effusion			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Joint hyperextension			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Joint lock			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	6 / 3576 (0.17%)	3 / 3581 (0.08%)	10 / 3576 (0.28%)
occurrences (all)	6	3	10
Joint stiffness			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	4 / 3576 (0.11%)
occurrences (all)	3	5	5
Joint swelling			
subjects affected / exposed	21 / 3576 (0.59%)	16 / 3581 (0.45%)	29 / 3576 (0.81%)
occurrences (all)	23	18	31
Joint warmth			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Kyphosis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	8 / 3576 (0.22%)
occurrences (all)	1	1	8
Ligamentitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Limb asymmetry			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Limb discomfort			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Limb mass			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	3
Lordosis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Low turnover osteopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	6 / 3576 (0.17%)	8 / 3581 (0.22%)	11 / 3576 (0.31%)
occurrences (all)	6	8	12
Mastication disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Meniscal degeneration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Metatarsalgia			
subjects affected / exposed	7 / 3576 (0.20%)	3 / 3581 (0.08%)	11 / 3576 (0.31%)
occurrences (all)	8	3	12
Mobility decreased			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Monarthrititis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Muscle atrophy			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)

occurrences (all)	2	1	3
Muscle contracture subjects affected / exposed	20 / 3576 (0.56%)	21 / 3581 (0.59%)	24 / 3576 (0.67%)
occurrences (all)	23	23	27
Muscle fatigue subjects affected / exposed	8 / 3576 (0.22%)	2 / 3581 (0.06%)	8 / 3576 (0.22%)
occurrences (all)	8	2	8
Muscle haemorrhage subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Muscle spasms subjects affected / exposed	140 / 3576 (3.91%)	163 / 3581 (4.55%)	201 / 3576 (5.62%)
occurrences (all)	155	179	236
Muscle tightness subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	2	1	5
Muscle twitching subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Muscular weakness subjects affected / exposed	20 / 3576 (0.56%)	19 / 3581 (0.53%)	32 / 3576 (0.89%)
occurrences (all)	22	21	34
Musculoskeletal chest pain subjects affected / exposed	21 / 3576 (0.59%)	14 / 3581 (0.39%)	37 / 3576 (1.03%)
occurrences (all)	21	14	38
Musculoskeletal discomfort subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	3 / 3576 (0.08%)
occurrences (all)	2	5	3
Musculoskeletal disorder subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain subjects affected / exposed	172 / 3576 (4.81%)	168 / 3581 (4.69%)	260 / 3576 (7.27%)
occurrences (all)	188	182	301
Musculoskeletal stiffness subjects affected / exposed	16 / 3576 (0.45%)	18 / 3581 (0.50%)	20 / 3576 (0.56%)

occurrences (all)	17	19	22
Myalgia			
subjects affected / exposed	127 / 3576 (3.55%)	114 / 3581 (3.18%)	175 / 3576 (4.89%)
occurrences (all)	150	129	206
Myofascial pain syndrome			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	4	1	4
Myofascitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Myositis ossificans			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Neck deformity			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	54 / 3576 (1.51%)	80 / 3581 (2.23%)	83 / 3576 (2.32%)
occurrences (all)	61	85	93
Nodal osteoarthritis			
subjects affected / exposed	7 / 3576 (0.20%)	3 / 3581 (0.08%)	9 / 3576 (0.25%)
occurrences (all)	7	3	9
Osteitis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	2	0	5
Osteoarthritis			
subjects affected / exposed	210 / 3576 (5.87%)	184 / 3581 (5.14%)	329 / 3576 (9.20%)
occurrences (all)	235	221	381
Osteochondritis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Osteochondrosis			
subjects affected / exposed	5 / 3576 (0.14%)	5 / 3581 (0.14%)	10 / 3576 (0.28%)



occurrences (all)	6	5	12
Osteolysis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Osteonecrosis			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Osteopenia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Osteoporosis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	9 / 3576 (0.25%)
occurrences (all)	2	1	9
Osteosclerosis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Pain in extremity			
subjects affected / exposed	299 / 3576 (8.36%)	278 / 3581 (7.76%)	407 / 3576 (11.38%)
occurrences (all)	356	353	510
Pain in jaw			
subjects affected / exposed	1 / 3576 (0.03%)	8 / 3581 (0.22%)	5 / 3576 (0.14%)
occurrences (all)	1	8	5
Palindromic rheumatism			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Periarthritis			
subjects affected / exposed	19 / 3576 (0.53%)	10 / 3581 (0.28%)	31 / 3576 (0.87%)
occurrences (all)	20	10	35
Periostitis			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	1	3	2
Peripheral arthritis			

subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	3	0	4
Plantar fasciitis			
subjects affected / exposed	5 / 3576 (0.14%)	10 / 3581 (0.28%)	10 / 3576 (0.28%)
occurrences (all)	5	10	10
Polyarthrititis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	2	1	5
Polymyalgia rheumatica			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	2	2	7
Rheumatic disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	4 / 3576 (0.11%)	0 / 3581 (0.00%)	8 / 3576 (0.22%)
occurrences (all)	4	0	8
Rib deformity			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	12 / 3576 (0.34%)	9 / 3581 (0.25%)	22 / 3576 (0.62%)
occurrences (all)	12	9	22
Sacroiliitis			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	4	2	6
Sarcopenia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Scoliosis			
subjects affected / exposed	8 / 3576 (0.22%)	8 / 3581 (0.22%)	18 / 3576 (0.50%)
occurrences (all)	8	9	18
Senile ankylosing vertebral hyperostosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1

Seronegative arthritis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Sinus tarsi syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Sjogren's syndrome			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	2	3	3
Spinal column stenosis			
subjects affected / exposed	5 / 3576 (0.14%)	2 / 3581 (0.06%)	8 / 3576 (0.22%)
occurrences (all)	6	2	9
Spinal deformity			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	1	2	3
Spinal disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Spinal flattening			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Spinal osteoarthritis			
subjects affected / exposed	86 / 3576 (2.40%)	86 / 3581 (2.40%)	138 / 3576 (3.86%)
occurrences (all)	105	105	183
Spinal pain			
subjects affected / exposed	42 / 3576 (1.17%)	33 / 3581 (0.92%)	57 / 3576 (1.59%)
occurrences (all)	43	37	62
Spondylitis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Spondylolisthesis			
subjects affected / exposed	6 / 3576 (0.17%)	7 / 3581 (0.20%)	10 / 3576 (0.28%)
occurrences (all)	6	7	11
Spondylolysis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0

Sympathetic posterior cervical syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Synovial cyst			
subjects affected / exposed	12 / 3576 (0.34%)	13 / 3581 (0.36%)	22 / 3576 (0.62%)
occurrences (all)	12	13	23
Synovitis			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	7 / 3576 (0.20%)
occurrences (all)	3	0	7
Systemic lupus erythematosus			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Temporomandibular joint syndrome			
subjects affected / exposed	7 / 3576 (0.20%)	5 / 3581 (0.14%)	10 / 3576 (0.28%)
occurrences (all)	8	5	12
Tendinous contracture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	6 / 3576 (0.17%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	6	2	7
Tendon pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Tendonitis			
subjects affected / exposed	20 / 3576 (0.56%)	28 / 3581 (0.78%)	37 / 3576 (1.03%)
occurrences (all)	20	28	39
Tenosynovitis			
subjects affected / exposed	8 / 3576 (0.22%)	8 / 3581 (0.22%)	16 / 3576 (0.45%)
occurrences (all)	8	9	17
Tenosynovitis stenosaurs			
subjects affected / exposed	8 / 3576 (0.22%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	8	7	9
Torticollis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2

Trigger finger subjects affected / exposed occurrences (all)	13 / 3576 (0.36%) 14	14 / 3581 (0.39%) 15	26 / 3576 (0.73%) 27
Vertebral foraminal stenosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 4
Vertebral osteophyte subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vertebral wedging subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Wrist deformity subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Endocrine disorders			
Adrenal disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Adrenal mass subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	1 / 3576 (0.03%) 1
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	1 / 3581 (0.03%) 1	6 / 3576 (0.17%) 6
Endocrine disorder subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Goitre subjects affected / exposed occurrences (all)	17 / 3576 (0.48%) 17	16 / 3581 (0.45%) 17	41 / 3576 (1.15%) 42
Haemorrhagic thyroid cyst subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Hyperparathyroidism			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Hyperthyroidism			
subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	2	5	6
Hypoparathyroidism			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hypothyroidic goitre			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	40 / 3576 (1.12%)	41 / 3581 (1.14%)	74 / 3576 (2.07%)
occurrences (all)	41	41	79
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Myxoedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Primary hypothyroidism			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Secondary hypothyroidism			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Thyroid atrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Thyroid cyst			

subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	5 / 3576 (0.14%) 5
Thyroid disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Thyroid mass subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	2 / 3581 (0.06%) 2	9 / 3576 (0.25%) 10
Thyroiditis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Thyroiditis chronic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Thyroiditis subacute subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Metabolism and nutrition disorders Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Acquired mixed hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Cachexia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 2	0 / 3576 (0.00%) 0
Calcium metabolism disorder subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Carbohydrate intolerance subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	7 / 3581 (0.20%) 7	8 / 3576 (0.22%) 8
Central obesity subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0

Cow's milk intolerance subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	32 / 3576 (0.89%) 32	24 / 3581 (0.67%) 24	48 / 3576 (1.34%) 48
Dehydration subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	3 / 3576 (0.08%) 4
Diabetes mellitus subjects affected / exposed occurrences (all)	31 / 3576 (0.87%) 31	34 / 3581 (0.95%) 35	61 / 3576 (1.71%) 64
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 7	7 / 3581 (0.20%) 7	12 / 3576 (0.34%) 13
Diabetic metabolic decompensation subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Dyslipidaemia subjects affected / exposed occurrences (all)	74 / 3576 (2.07%) 74	81 / 3581 (2.26%) 81	137 / 3576 (3.83%) 143
Electrolyte imbalance subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	5 / 3576 (0.14%) 5
Fluid overload subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Fluid retention subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Folate deficiency subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Food intolerance subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1



Glucose tolerance impaired subjects affected / exposed occurrences (all)	12 / 3576 (0.34%) 12	16 / 3581 (0.45%) 16	24 / 3576 (0.67%) 25
Gout subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 12	3 / 3581 (0.08%) 3	14 / 3576 (0.39%) 19
Hyper HDL cholesterolaemia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Hyperammonaemia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 5	1 / 3581 (0.03%) 1	19 / 3576 (0.53%) 20
Hyperchloraemia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Hypercholesterolaemia subjects affected / exposed occurrences (all)	42 / 3576 (1.17%) 42	45 / 3581 (1.26%) 45	72 / 3576 (2.01%) 74
Hyperglycaemia subjects affected / exposed occurrences (all)	24 / 3576 (0.67%) 26	27 / 3581 (0.75%) 28	41 / 3576 (1.15%) 48
Hyperkalaemia subjects affected / exposed occurrences (all)	11 / 3576 (0.31%) 11	9 / 3581 (0.25%) 9	18 / 3576 (0.50%) 18
Hyperlipidaemia subjects affected / exposed occurrences (all)	21 / 3576 (0.59%) 21	12 / 3581 (0.34%) 12	31 / 3576 (0.87%) 31
Hypermagnesaemia subjects affected / exposed occurrences (all)	4 / 3576 (0.11%) 4	1 / 3581 (0.03%) 1	7 / 3576 (0.20%) 8
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	0 / 3576 (0.00%) 0

Hyperproteinaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hypertriglyceridaemia			
subjects affected / exposed	6 / 3576 (0.17%)	17 / 3581 (0.47%)	13 / 3576 (0.36%)
occurrences (all)	6	17	13
Hyperuricaemia			
subjects affected / exposed	8 / 3576 (0.22%)	10 / 3581 (0.28%)	14 / 3576 (0.39%)
occurrences (all)	8	10	14
Hypervitaminosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	0	1	3
Hypochloraemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Hypoglycaemia			
subjects affected / exposed	8 / 3576 (0.22%)	11 / 3581 (0.31%)	12 / 3576 (0.34%)
occurrences (all)	8	13	13
Hypokalaemia			
subjects affected / exposed	10 / 3576 (0.28%)	15 / 3581 (0.42%)	24 / 3576 (0.67%)
occurrences (all)	10	15	24
Hypomagnesaemia			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	3	0	4
Hyponatraemia			
subjects affected / exposed	6 / 3576 (0.17%)	10 / 3581 (0.28%)	17 / 3576 (0.48%)
occurrences (all)	7	10	19
Hypophosphataemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2

Hypoproteinaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Impaired fasting glucose			
subjects affected / exposed	11 / 3576 (0.31%)	10 / 3581 (0.28%)	14 / 3576 (0.39%)
occurrences (all)	11	10	14
Increased appetite			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Insulin resistance			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Iron deficiency			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Lactose intolerance			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Latent tetany			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Lipid metabolism disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	4
Malnutrition			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Metabolic disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Metabolic syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Obesity			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	2	0	6
Overweight			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Periarthritis calcarea			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Plasma protein metabolism disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	17 / 3576 (0.48%)	21 / 3581 (0.59%)	35 / 3576 (0.98%)
occurrences (all)	17	22	36
Underweight			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Vitamin B complex deficiency			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Vitamin B12 deficiency			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	8 / 3576 (0.22%)
occurrences (all)	4	4	9
Vitamin D deficiency			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	6 / 3576 (0.17%)
occurrences (all)	1	4	6
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Abscess			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Abscess bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Abscess jaw			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Abscess limb			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	4	3	5
Abscess neck			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Abscess of eyelid			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Abscess oral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Abscess rupture			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	4	3	7
Actinomycotic pulmonary infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	4 / 3576 (0.11%)
occurrences (all)	3	6	4
Alphaviral infection			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Amoebiasis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)

occurrences (all)	1	2	3
Amoebic dysentery			
subjects affected / exposed	2 / 3576 (0.06%)	5 / 3581 (0.14%)	2 / 3576 (0.06%)
occurrences (all)	2	5	2
Anal abscess			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Angular cheilitis			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	1	3	1
Appendicitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Arthritis bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Ascariasis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Asymptomatic bacteriuria			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	7 / 3576 (0.20%)
occurrences (all)	2	4	7
Atypical pneumonia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Bacteraemia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bacterial diarrhoea			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	3	2	4
Bacterial infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Bacterial rhinitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Bacterial vaginosis			
subjects affected / exposed	3 / 3576 (0.08%)	7 / 3581 (0.20%)	4 / 3576 (0.11%)
occurrences (all)	3	7	4
Bacteriuria			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Blastocystis infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Borrelia infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bronchiolitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	0	0	3
Bronchitis			
subjects affected / exposed	90 / 3576 (2.52%)	80 / 3581 (2.23%)	162 / 3576 (4.53%)
occurrences (all)	97	83	196
Bronchitis bacterial			
subjects affected / exposed	21 / 3576 (0.59%)	12 / 3581 (0.34%)	24 / 3576 (0.67%)
occurrences (all)	22	14	28
Bronchitis viral			
subjects affected / exposed	6 / 3576 (0.17%)	3 / 3581 (0.08%)	9 / 3576 (0.25%)
occurrences (all)	6	3	9
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cellulitis			
subjects affected / exposed	16 / 3576 (0.45%)	13 / 3581 (0.36%)	24 / 3576 (0.67%)
occurrences (all)	16	13	24
Chikungunya virus infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Cholecystitis infective			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Chronic hepatitis C			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Chronic sinusitis			
subjects affected / exposed	5 / 3576 (0.14%)	2 / 3581 (0.06%)	11 / 3576 (0.31%)
occurrences (all)	5	2	11
Chronic tonsillitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	24 / 3576 (0.67%)	34 / 3581 (0.95%)	42 / 3576 (1.17%)
occurrences (all)	25	36	43
Conjunctivitis bacterial			
subjects affected / exposed	8 / 3576 (0.22%)	11 / 3581 (0.31%)	9 / 3576 (0.25%)
occurrences (all)	8	11	9
Conjunctivitis viral			



subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Cystitis			
subjects affected / exposed	49 / 3576 (1.37%)	56 / 3581 (1.56%)	84 / 3576 (2.35%)
occurrences (all)	61	62	114
Cystitis bacterial			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	8	12	10
Cystitis escherichia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cystitis klebsiella			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cystitis viral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Dacryocystitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	2	0	2
Dengue fever			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	7 / 3576 (0.20%)
occurrences (all)	0	0	8
Dental fistula			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Dental gangrene			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dermatitis infected			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dermatophytosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dermatophytosis of nail			

subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Diarrhoea infectious			
subjects affected / exposed	3 / 3576 (0.08%)	7 / 3581 (0.20%)	3 / 3576 (0.08%)
occurrences (all)	3	7	3
Diverticulitis			
subjects affected / exposed	4 / 3576 (0.11%)	6 / 3581 (0.17%)	9 / 3576 (0.25%)
occurrences (all)	4	6	9
Dysentery			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	13 / 3576 (0.36%)	8 / 3581 (0.22%)	16 / 3576 (0.45%)
occurrences (all)	13	8	16
Ear infection bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Ear infection viral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Eczema impetiginous			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Eczema infected			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Enteritis infectious			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Enterobiasis			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Enterocolitis infectious			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Erysipelas			

subjects affected / exposed	6 / 3576 (0.17%)	5 / 3581 (0.14%)	14 / 3576 (0.39%)
occurrences (all)	7	5	15
Erythema migrans			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Escherichia urinary tract infection			
subjects affected / exposed	7 / 3576 (0.20%)	5 / 3581 (0.14%)	12 / 3576 (0.34%)
occurrences (all)	8	5	13
Eye infection			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	1	4
Eye infection bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Eyelid infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Flavivirus infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	0	0	5
Folliculitis			
subjects affected / exposed	5 / 3576 (0.14%)	4 / 3581 (0.11%)	5 / 3576 (0.14%)
occurrences (all)	5	4	5
Fungal infection			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Fungal skin infection			
subjects affected / exposed	10 / 3576 (0.28%)	9 / 3581 (0.25%)	18 / 3576 (0.50%)
occurrences (all)	10	9	18
Furuncle			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	12 / 3576 (0.34%)
occurrences (all)	8	4	13
Gastric infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gastric ulcer helicobacter			

subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gastritis viral			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Gastroenteritis			
subjects affected / exposed	57 / 3576 (1.59%)	49 / 3581 (1.37%)	83 / 3576 (2.32%)
occurrences (all)	62	53	93
Gastroenteritis bacterial			
subjects affected / exposed	5 / 3576 (0.14%)	6 / 3581 (0.17%)	6 / 3576 (0.17%)
occurrences (all)	5	6	6
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Gastroenteritis viral			
subjects affected / exposed	47 / 3576 (1.31%)	43 / 3581 (1.20%)	63 / 3576 (1.76%)
occurrences (all)	49	43	66
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal candidiasis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gastrointestinal infection			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	4	3	5
Gastrointestinal viral infection			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	3	3	6
Genital herpes			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	4 / 3576 (0.11%)
occurrences (all)	3	5	10
Genital infection fungal			

subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Giardiasis			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	1	3	2
Gingival abscess			
subjects affected / exposed	5 / 3576 (0.14%)	0 / 3581 (0.00%)	6 / 3576 (0.17%)
occurrences (all)	5	0	6
Gingivitis			
subjects affected / exposed	22 / 3576 (0.62%)	32 / 3581 (0.89%)	26 / 3576 (0.73%)
occurrences (all)	22	32	28
Groin abscess			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Haemophilus infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Helicobacter gastritis			
subjects affected / exposed	5 / 3576 (0.14%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	6	4	10
Helicobacter infection			
subjects affected / exposed	10 / 3576 (0.28%)	11 / 3581 (0.31%)	26 / 3576 (0.73%)
occurrences (all)	10	11	26
Helminthic infection			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Hepatitis B			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hepatitis C			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	3
Hepatitis viral			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Herpes dermatitis			

subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Herpes ophthalmic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Herpes simplex			
subjects affected / exposed	3 / 3576 (0.08%)	6 / 3581 (0.17%)	5 / 3576 (0.14%)
occurrences (all)	5	6	10
Herpes virus infection			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	4	3	6
Herpes zoster			
subjects affected / exposed	22 / 3576 (0.62%)	33 / 3581 (0.92%)	61 / 3576 (1.71%)
occurrences (all)	24	33	63
Herpes zoster infection neurological			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Herpes zoster oticus			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hookworm infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	6 / 3576 (0.17%)	2 / 3581 (0.06%)	11 / 3576 (0.31%)
occurrences (all)	6	2	11
Impetigo			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Incision site infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Infected bite			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Infected cyst			

subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Infected dermal cyst			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Infected skin ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Infection			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Infection parasitic			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Influenza			
subjects affected / exposed	180 / 3576 (5.03%)	169 / 3581 (4.72%)	240 / 3576 (6.71%)
occurrences (all)	221	207	306
Injection site infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Kaposi's varicelliform eruption			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Keratitis viral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Labyrinthitis			
subjects affected / exposed	12 / 3576 (0.34%)	7 / 3581 (0.20%)	21 / 3576 (0.59%)
occurrences (all)	13	7	25

Laryngitis			
subjects affected / exposed	13 / 3576 (0.36%)	16 / 3581 (0.45%)	18 / 3576 (0.50%)
occurrences (all)	14	17	23
Laryngitis bacterial			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Laryngitis viral			
subjects affected / exposed	6 / 3576 (0.17%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	6	2	6
Latent syphilis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	8 / 3576 (0.22%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	8	4	9
Lower respiratory tract infection			
subjects affected / exposed	18 / 3576 (0.50%)	18 / 3581 (0.50%)	36 / 3576 (1.01%)
occurrences (all)	22	18	55
Lower respiratory tract infection bacterial			
subjects affected / exposed	3 / 3576 (0.08%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	4	5	5
Lower respiratory tract infection viral			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Lung infection			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	0	4	3
Lyme disease			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	4	1	6
Malaria			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mastitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)



occurrences (all)	0	0	0
Mastitis bacterial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Mastoiditis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mumps			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Mycobacterial infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Myringitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Nail bed infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nail bed infection bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nasal abscess			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	439 / 3576 (12.28%)	460 / 3581 (12.85%)	622 / 3576 (17.39%)
occurrences (all)	545	570	936
Nematodiasis			

subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Onychomycosis			
subjects affected / exposed	10 / 3576 (0.28%)	16 / 3581 (0.45%)	21 / 3576 (0.59%)
occurrences (all)	10	16	22
Oral bacterial infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Oral candidiasis			
subjects affected / exposed	5 / 3576 (0.14%)	6 / 3581 (0.17%)	9 / 3576 (0.25%)
occurrences (all)	5	6	11
Oral fungal infection			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	6 / 3576 (0.17%)
occurrences (all)	3	1	6
Oral herpes			
subjects affected / exposed	17 / 3576 (0.48%)	22 / 3581 (0.61%)	22 / 3576 (0.62%)
occurrences (all)	18	22	23
Oral infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Oral viral infection			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Osteomyelitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis chronic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Otitis externa			

subjects affected / exposed	1 / 3576 (0.03%)	9 / 3581 (0.25%)	6 / 3576 (0.17%)
occurrences (all)	1	10	6
Otitis externa bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Otitis media			
subjects affected / exposed	3 / 3576 (0.08%)	5 / 3581 (0.14%)	8 / 3576 (0.22%)
occurrences (all)	3	5	8
Otitis media acute			
subjects affected / exposed	4 / 3576 (0.11%)	5 / 3581 (0.14%)	7 / 3576 (0.20%)
occurrences (all)	4	5	8
Otitis media bacterial			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	3	2	4
Otitis media chronic			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Otosalpingitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Parasitic gastroenteritis			
subjects affected / exposed	7 / 3576 (0.20%)	2 / 3581 (0.06%)	10 / 3576 (0.28%)
occurrences (all)	7	2	10
Paronychia			
subjects affected / exposed	6 / 3576 (0.17%)	4 / 3581 (0.11%)	8 / 3576 (0.22%)
occurrences (all)	8	4	10
Parotitis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	4
Pelvic inflammatory disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Peptic ulcer helicobacter			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Perichondritis			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pericoronitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	31 / 3576 (0.87%)	20 / 3581 (0.56%)	47 / 3576 (1.31%)
occurrences (all)	33	23	50
Periorbital cellulitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	31 / 3576 (0.87%)	36 / 3581 (1.01%)	61 / 3576 (1.71%)
occurrences (all)	36	39	72
Pharyngitis bacterial			
subjects affected / exposed	9 / 3576 (0.25%)	7 / 3581 (0.20%)	10 / 3576 (0.28%)
occurrences (all)	9	8	10
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Pilonidal cyst			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	36 / 3576 (1.01%)	35 / 3581 (0.98%)	64 / 3576 (1.79%)
occurrences (all)	38	35	81
Pneumonia adenoviral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			

subjects affected / exposed	10 / 3576 (0.28%)	6 / 3581 (0.17%)	13 / 3576 (0.36%)
occurrences (all)	11	6	15
Pneumonia cryptococcal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pneumonia viral			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	0	1	3
Post viral fatigue syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Postoperative wound infection			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	1	5
Pulmonary tuberculosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pulpitis dental			
subjects affected / exposed	11 / 3576 (0.31%)	7 / 3581 (0.20%)	14 / 3576 (0.39%)
occurrences (all)	14	7	17
Pyelonephritis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pyelonephritis acute			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pyelonephritis chronic			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pyuria			

subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Respiratory tract infection			
subjects affected / exposed	13 / 3576 (0.36%)	19 / 3581 (0.53%)	34 / 3576 (0.95%)
occurrences (all)	15	19	39
Respiratory tract infection bacterial			
subjects affected / exposed	5 / 3576 (0.14%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	5	5	6
Respiratory tract infection viral			
subjects affected / exposed	23 / 3576 (0.64%)	10 / 3581 (0.28%)	29 / 3576 (0.81%)
occurrences (all)	28	12	38
Rhinitis			
subjects affected / exposed	35 / 3576 (0.98%)	38 / 3581 (1.06%)	56 / 3576 (1.57%)
occurrences (all)	37	39	59
Root canal infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sialoadenitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sinobronchitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	27 / 3576 (0.76%)	51 / 3581 (1.42%)	55 / 3576 (1.54%)
occurrences (all)	28	54	62
Sinusitis bacterial			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	7 / 3576 (0.20%)
occurrences (all)	6	3	8
Skin bacterial infection			

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin candida			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Skin infection			
subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	5 / 3576 (0.14%)
occurrences (all)	1	4	5
Soft tissue infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Staphylococcal infection			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Stoma site abscess			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Streptococcal infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Streptococcal urinary tract infection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	1	4	5
Superinfection			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Superinfection bacterial			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Tick-borne viral encephalitis			

subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	2	0	2
Tinea capitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tinea cruris			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tinea infection			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Tinea pedis			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	13 / 3576 (0.36%)
occurrences (all)	4	3	13
Tinea versicolour			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	14 / 3576 (0.39%)	18 / 3581 (0.50%)	22 / 3576 (0.62%)
occurrences (all)	15	18	25
Tonsillitis bacterial			
subjects affected / exposed	5 / 3576 (0.14%)	6 / 3581 (0.17%)	5 / 3576 (0.14%)
occurrences (all)	5	6	5
Tooth abscess			
subjects affected / exposed	11 / 3576 (0.31%)	13 / 3581 (0.36%)	22 / 3576 (0.62%)
occurrences (all)	12	13	23
Tooth infection			
subjects affected / exposed	8 / 3576 (0.22%)	12 / 3581 (0.34%)	17 / 3576 (0.48%)
occurrences (all)	10	12	20
Tracheitis			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Tracheobronchitis			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Trichuriasis			



subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tuberculosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	172 / 3576 (4.81%)	161 / 3581 (4.50%)	255 / 3576 (7.13%)
occurrences (all)	254	232	453
Upper respiratory tract infection bacterial			
subjects affected / exposed	15 / 3576 (0.42%)	19 / 3581 (0.53%)	21 / 3576 (0.59%)
occurrences (all)	16	20	22
Urethritis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	142 / 3576 (3.97%)	130 / 3581 (3.63%)	263 / 3576 (7.35%)
occurrences (all)	156	147	331
Urinary tract infection bacterial			
subjects affected / exposed	41 / 3576 (1.15%)	23 / 3581 (0.64%)	43 / 3576 (1.20%)
occurrences (all)	44	26	47
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection staphylococcal			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Urinary tract infection viral			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Vaginal cellulitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	4	4	11

Vaginitis bacterial subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	3 / 3581 (0.08%) 3	0 / 3576 (0.00%) 0
Varicella subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Viraemia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	2 / 3581 (0.06%) 2	2 / 3576 (0.06%) 2
Viral diarrhoea subjects affected / exposed occurrences (all)	32 / 3576 (0.89%) 34	27 / 3581 (0.75%) 28	34 / 3576 (0.95%) 36
Viral hepatitis carrier subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Viral infection subjects affected / exposed occurrences (all)	29 / 3576 (0.81%) 30	30 / 3581 (0.84%) 32	45 / 3576 (1.26%) 47
Viral labyrinthitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	2 / 3581 (0.06%) 2	1 / 3576 (0.03%) 1
Viral pharyngitis subjects affected / exposed occurrences (all)	15 / 3576 (0.42%) 18	12 / 3581 (0.34%) 12	17 / 3576 (0.48%) 20
Viral rash subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Viral rhinitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 3	1 / 3576 (0.03%) 1
Viral sinusitis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Viral skin infection subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	227 / 3576 (6.35%) 312	206 / 3581 (5.75%) 283	263 / 3576 (7.35%) 394
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	6 / 3576 (0.17%) 6	3 / 3581 (0.08%) 4	8 / 3576 (0.22%) 9
Vulvovaginitis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	5 / 3576 (0.14%) 6	2 / 3581 (0.06%) 2	8 / 3576 (0.22%) 9
Wound infection bacterial subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Zika virus infection subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Vascular disorders			
Aneurysm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Angiosclerosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Aortic aneurysm subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	5 / 3576 (0.14%) 5
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	6 / 3576 (0.17%) 6	11 / 3581 (0.31%) 12	30 / 3576 (0.84%) 30
Aortic calcification subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)

occurrences (all)	1	0	3
Aortic dilatation			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	2	2	5
Aortic dissection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Aortic elongation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Aortic stenosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Aortic thrombosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Arterial disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Arterial occlusive disease			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Arterial stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Arteriosclerosis			
subjects affected / exposed	14 / 3576 (0.39%)	15 / 3581 (0.42%)	33 / 3576 (0.92%)
occurrences (all)	15	16	35
Blood pressure fluctuation			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	5	1	5
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Capillary fragility			

subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Capillary leak syndrome			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Diastolic hypotension			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Embolism arterial			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Essential hypertension			
subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	6 / 3576 (0.17%)
occurrences (all)	4	4	6
Extravasation blood			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	2	3	2
Haematoma			
subjects affected / exposed	20 / 3576 (0.56%)	20 / 3581 (0.56%)	27 / 3576 (0.76%)
occurrences (all)	25	23	32
Haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	12 / 3576 (0.34%)	11 / 3581 (0.31%)	12 / 3576 (0.34%)
occurrences (all)	13	12	13
Hyperaemia			

subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	260 / 3576 (7.27%)	219 / 3581 (6.12%)	411 / 3576 (11.49%)
occurrences (all)	274	244	461
Hypertensive angiopathy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Hypertensive crisis			
subjects affected / exposed	7 / 3576 (0.20%)	12 / 3581 (0.34%)	16 / 3576 (0.45%)
occurrences (all)	8	13	17
Hypertensive emergency			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	3
Hypotension			
subjects affected / exposed	20 / 3576 (0.56%)	7 / 3581 (0.20%)	24 / 3576 (0.67%)
occurrences (all)	21	7	27
Hypovolaemic shock			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	2	0	2
Intermittent claudication			
subjects affected / exposed	1 / 3576 (0.03%)	3 / 3581 (0.08%)	3 / 3576 (0.08%)
occurrences (all)	1	3	3
Ischaemia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Labile blood pressure			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Lymphoedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Lymphostasis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2

Microangiopathy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypertension			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Peripheral arterial occlusive disease			
subjects affected / exposed	5 / 3576 (0.14%)	8 / 3581 (0.22%)	9 / 3576 (0.25%)
occurrences (all)	6	8	11
Peripheral artery occlusion			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	3
Peripheral artery stenosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Peripheral circulatory failure			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Peripheral coldness			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Peripheral embolism			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Peripheral ischaemia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Peripheral vascular disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	1	0	5

Peripheral venous disease subjects affected / exposed occurrences (all)	14 / 3576 (0.39%) 15	19 / 3581 (0.53%) 21	26 / 3576 (0.73%) 27
Phlebitis subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	3 / 3581 (0.08%) 3	6 / 3576 (0.17%) 6
Phlebitis superficial subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	3 / 3581 (0.08%) 3	3 / 3576 (0.08%) 3
Phlebolith subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Poor peripheral circulation subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Post thrombotic syndrome subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Raynaud's phenomenon subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	4 / 3576 (0.11%) 4
Shock subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Spider vein subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Subgaleal haematoma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Superior vena cava syndrome subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Temporal arteritis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0



Thrombophlebitis subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	3 / 3581 (0.08%) 3	7 / 3576 (0.20%) 7
Thrombophlebitis superficial subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 2	5 / 3576 (0.14%) 6
Thrombosed varicose vein subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Thrombosis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Varicophlebitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Varicose ulceration subjects affected / exposed occurrences (all)	7 / 3576 (0.20%) 8	2 / 3581 (0.06%) 2	9 / 3576 (0.25%) 10
Varicose vein subjects affected / exposed occurrences (all)	25 / 3576 (0.70%) 26	17 / 3581 (0.47%) 17	46 / 3576 (1.29%) 50
Varicose vein ruptured subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Vascular calcification subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Vascular fragility subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Vascular insufficiency subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Vascular pain subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Vascular rupture subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Vasculitis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	1 / 3576 (0.03%) 1
Vasodilatation subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Vein disorder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Venous thrombosis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Withdrawal hypertension subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Surgical and medical procedures			
Abdominal hernia repair subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Artificial crown procedure subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Bladder repair subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Bunion operation subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Cancer surgery subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Cataract operation			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Colectomy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Colostomy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Corneal transplant			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cyst removal			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dental care			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Dental cleaning			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Dental prosthesis placement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Dermatofibroma removal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Endodontic procedure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Eye operation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hip arthroplasty			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Hypotensive anaesthesia procedure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia repair			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc operation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Intraocular lens implant			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Large intestinal polypectomy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Lip operation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nail operation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Peripheral nerve operation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Plastic surgery to the face			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Rotator cuff repair			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Skin neoplasm excision			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Spinal fusion surgery			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	0	0	1
Suture insertion			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	2
Thyroidectomy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Toe operation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Tooth extraction			
subjects affected / exposed	4 / 3576 (0.11%)	8 / 3581 (0.22%)	15 / 3576 (0.42%)
occurrences (all)	4	9	16
Wisdom teeth removal			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	3	0	4
Adenocarcinoma gastric			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Adenoma benign			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Adrenal neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Angiomyolipoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Anogenital warts			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0

Basal cell carcinoma subjects affected / exposed occurrences (all)	11 / 3576 (0.31%) 12	6 / 3581 (0.17%) 7	17 / 3576 (0.48%) 19
Benign bone neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Benign breast neoplasm subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	4 / 3576 (0.11%) 4
Benign gastric neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Benign lung neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Benign neoplasm subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Benign neoplasm of adrenal gland subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Benign neoplasm of bladder subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Benign neoplasm of cornea subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Benign neoplasm of skin subjects affected / exposed occurrences (all)	3 / 3576 (0.08%) 3	1 / 3581 (0.03%) 1	4 / 3576 (0.11%) 4
Benign neoplasm of thyroid gland subjects affected / exposed occurrences (all)	9 / 3576 (0.25%) 9	7 / 3581 (0.20%) 7	13 / 3576 (0.36%) 14
Benign ovarian tumour subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Benign pancreatic neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Benign pleural neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Benign renal neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Benign salivary gland neoplasm subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Benign soft tissue neoplasm subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Bowen's disease subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	3 / 3581 (0.08%) 3	0 / 3576 (0.00%) 0
Breast cancer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Breast fibroma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Cancer pain subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Chronic lymphocytic leukaemia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Colon adenoma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	3 / 3581 (0.08%) 3	2 / 3576 (0.06%) 2
Colon cancer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	2 / 3581 (0.06%) 2	0 / 3576 (0.00%) 0

Ear neoplasm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Enchondromatosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Eye naevus			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Fibroadenoma of breast			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Fibroma			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	1	1	4
Fibromatosis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Fibrous histiocytoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Gastric neoplasm			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Haemangioma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Haemangioma of bone			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Haemangioma of liver			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2



Haemangioma of skin			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hair follicle tumour benign			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hepatic neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Intraductal papilloma of breast			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Juvenile melanoma benign			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Keratoacanthoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Kidney angiomyolipoma			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Leiomyoma			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	2	1	5
Lipofibroma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	2 / 3576 (0.06%)	6 / 3581 (0.17%)	6 / 3576 (0.17%)
occurrences (all)	2	6	6
Lymphoproliferative disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0

Malignant melanoma in situ subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Melanocytic naevus subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	5 / 3576 (0.14%) 5
Meningioma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Meningioma benign subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Metastases to lung subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Metastases to peritoneum subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Non-Hodgkin's lymphoma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Oral haemangioma subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Ovarian cancer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Papillary thyroid cancer subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Polycythaemia vera subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Pyogenic granuloma subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0

Renal neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	6 / 3576 (0.17%)	6 / 3581 (0.17%)	9 / 3576 (0.25%)
occurrences (all)	6	7	10
Skin cancer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Skin papilloma			
subjects affected / exposed	2 / 3576 (0.06%)	6 / 3581 (0.17%)	3 / 3576 (0.08%)
occurrences (all)	2	6	3
Squamous cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Sweat gland tumour			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Thyroid adenoma			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Thyroid neoplasm			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Transitional cell carcinoma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Uterine leiomyoma			
subjects affected / exposed	0 / 3576 (0.00%)	4 / 3581 (0.11%)	3 / 3576 (0.08%)
occurrences (all)	0	4	3
Immune system disorders			
Allergic oedema			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)

occurrences (all)	2	1	4
Allergy to animal			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Allergy to arthropod bite			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Allergy to arthropod sting			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Allergy to chemicals			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Allergy to plants			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Allergy to vaccine			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Atopy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Contrast media allergy			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Drug hypersensitivity			
subjects affected / exposed	5 / 3576 (0.14%)	3 / 3581 (0.08%)	14 / 3576 (0.39%)
occurrences (all)	5	3	14
Food allergy			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	2 / 3576 (0.06%)
occurrences (all)	0	3	2
Hypersensitivity			
subjects affected / exposed	4 / 3576 (0.11%)	5 / 3581 (0.14%)	10 / 3576 (0.28%)
occurrences (all)	4	5	10
Mite allergy			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)

occurrences (all)	2	0	2
Multiple allergies			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Rubber sensitivity			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Seasonal allergy			
subjects affected / exposed	9 / 3576 (0.25%)	6 / 3581 (0.17%)	18 / 3576 (0.50%)
occurrences (all)	9	6	19
Transplant rejection			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Type I hypersensitivity			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Bereavement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Dental prosthesis user			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Family stress			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Immobile			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Menopause			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Stress at work			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
General disorders and administration			

site conditions			
Administration site erythema			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Administration site pain			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Administration site reaction			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Adverse drug reaction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Application site bruise			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Application site dermatitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Application site eczema			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Application site pruritus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Application site rash			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Asthenia			
subjects affected / exposed	79 / 3576 (2.21%)	84 / 3581 (2.35%)	111 / 3576 (3.10%)
occurrences (all)	94	97	135
Axillary pain			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Calcinosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Catheter site haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Catheter site pain			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Chest discomfort			
subjects affected / exposed	3 / 3576 (0.08%)	6 / 3581 (0.17%)	6 / 3576 (0.17%)
occurrences (all)	3	6	7
Chest pain			
subjects affected / exposed	30 / 3576 (0.84%)	30 / 3581 (0.84%)	44 / 3576 (1.23%)
occurrences (all)	30	31	44
Chills			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	3	3	4
Crying			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cyst			
subjects affected / exposed	4 / 3576 (0.11%)	7 / 3581 (0.20%)	7 / 3576 (0.20%)
occurrences (all)	4	7	7
Discomfort			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Drug intolerance			
subjects affected / exposed	7 / 3576 (0.20%)	10 / 3581 (0.28%)	12 / 3576 (0.34%)
occurrences (all)	7	10	12
Exercise tolerance decreased			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	1	2	4
Face oedema			
subjects affected / exposed	4 / 3576 (0.11%)	5 / 3581 (0.14%)	6 / 3576 (0.17%)
occurrences (all)	4	5	6
Facial pain			
subjects affected / exposed	6 / 3576 (0.17%)	4 / 3581 (0.11%)	11 / 3576 (0.31%)

occurrences (all)	7	4	12
Fat tissue increased			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	52 / 3576 (1.45%)	48 / 3581 (1.34%)	61 / 3576 (1.71%)
occurrences (all)	59	56	70
Feeling abnormal			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Feeling cold			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	2 / 3576 (0.06%)	8 / 3581 (0.22%)	4 / 3576 (0.11%)
occurrences (all)	2	10	4
Feeling of body temperature change			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	4 / 3576 (0.11%)	5 / 3581 (0.14%)	8 / 3576 (0.22%)
occurrences (all)	4	6	8
General physical health deterioration			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Generalised oedema			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	0	2	3
Granuloma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Impaired healing			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Implant site cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)



occurrences (all)	1	0	1
Implant site haematoma subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Implant site pain subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Inflammation subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	3	1	3
Influenza like illness subjects affected / exposed	39 / 3576 (1.09%)	29 / 3581 (0.81%)	54 / 3576 (1.51%)
occurrences (all)	43	30	62
Infusion site bruising subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Infusion site extravasation subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Injection site bruising subjects affected / exposed	20 / 3576 (0.56%)	29 / 3581 (0.81%)	21 / 3576 (0.59%)
occurrences (all)	24	32	25
Injection site cyst subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Injection site dermatitis subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Injection site erythema subjects affected / exposed	5 / 3576 (0.14%)	54 / 3581 (1.51%)	5 / 3576 (0.14%)
occurrences (all)	5	110	5
Injection site haematoma subjects affected / exposed	6 / 3576 (0.17%)	8 / 3581 (0.22%)	6 / 3576 (0.17%)
occurrences (all)	6	9	6
Injection site haemorrhage subjects affected / exposed	13 / 3576 (0.36%)	13 / 3581 (0.36%)	14 / 3576 (0.39%)

occurrences (all)	15	13	16
Injection site hypersensitivity subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	1 / 3576 (0.03%)
occurrences (all)	1	8	1
Injection site induration subjects affected / exposed	1 / 3576 (0.03%)	4 / 3581 (0.11%)	1 / 3576 (0.03%)
occurrences (all)	1	5	1
Injection site inflammation subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Injection site mass subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Injection site nodule subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Injection site oedema subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	3	1
Injection site pain subjects affected / exposed	46 / 3576 (1.29%)	62 / 3581 (1.73%)	47 / 3576 (1.31%)
occurrences (all)	75	92	76
Injection site papule subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Injection site paraesthesia subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	10	1	10
Injection site pruritus subjects affected / exposed	7 / 3576 (0.20%)	27 / 3581 (0.75%)	7 / 3576 (0.20%)
occurrences (all)	8	51	8
Injection site rash subjects affected / exposed	2 / 3576 (0.06%)	13 / 3581 (0.36%)	2 / 3576 (0.06%)
occurrences (all)	3	23	3
Injection site reaction subjects affected / exposed	1 / 3576 (0.03%)	5 / 3581 (0.14%)	1 / 3576 (0.03%)

occurrences (all)	1	5	1
Injection site swelling			
subjects affected / exposed	1 / 3576 (0.03%)	16 / 3581 (0.45%)	1 / 3576 (0.03%)
occurrences (all)	1	36	1
Injection site urticaria			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	1 / 3576 (0.03%)
occurrences (all)	0	8	1
Injection site warmth			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Injury associated with device			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Ischaemic ulcer			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Local swelling			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	1	2
Localised oedema			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Malaise			
subjects affected / exposed	18 / 3576 (0.50%)	17 / 3581 (0.47%)	29 / 3576 (0.81%)
occurrences (all)	20	20	32
Mass			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Medical device pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Mucosal inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)

occurrences (all)	0	2	0
Nodule			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	4	1	4
Non-cardiac chest pain			
subjects affected / exposed	23 / 3576 (0.64%)	26 / 3581 (0.73%)	42 / 3576 (1.17%)
occurrences (all)	23	27	47
Oedema			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Oedema peripheral			
subjects affected / exposed	67 / 3576 (1.87%)	86 / 3581 (2.40%)	97 / 3576 (2.71%)
occurrences (all)	74	96	114
Pain			
subjects affected / exposed	40 / 3576 (1.12%)	39 / 3581 (1.09%)	56 / 3576 (1.57%)
occurrences (all)	42	42	59
Pelvic mass			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Peripheral swelling			
subjects affected / exposed	20 / 3576 (0.56%)	20 / 3581 (0.56%)	30 / 3576 (0.84%)
occurrences (all)	22	23	32
Polyp			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Puncture site haemorrhage			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Puncture site oedema			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Puncture site pain			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Puncture site reaction			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)

occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	66 / 3576 (1.85%)	49 / 3581 (1.37%)	74 / 3576 (2.07%)
occurrences (all)	79	61	88
Sensation of foreign body			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Sense of oppression			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Soft tissue inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Suprapubic pain			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Swelling			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Temperature intolerance			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	3	0	3
Ulcer haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Vaccination site bruising			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vaccination site induration			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)

occurrences (all)	0	1	0
Vessel puncture site bruise subjects affected / exposed	4 / 3576 (0.11%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	4	4	4
Vessel puncture site erythema subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site haematoma subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	2	0	3
Vessel puncture site haemorrhage subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Vessel puncture site pain subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site reaction subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Xerosis subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Psychiatric disorders			
Abnormal behaviour subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	2	2	2
Abnormal dreams subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Acute stress disorder subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Adjustment disorder subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	3	2	3
Adjustment disorder with depressed			

mood			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	4 / 3576 (0.11%)
occurrences (all)	4	3	4
Affective disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Agitation			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Alcohol abuse			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Alcoholic hangover			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	27 / 3576 (0.76%)	25 / 3581 (0.70%)	37 / 3576 (1.03%)
occurrences (all)	29	25	39
Anxiety disorder			
subjects affected / exposed	7 / 3576 (0.20%)	2 / 3581 (0.06%)	16 / 3576 (0.45%)
occurrences (all)	8	2	17
Anxiety disorder due to a general medical condition			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bipolar II disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Bipolar disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bruxism			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bulimia nervosa			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Cardiovascular somatic symptom disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Confusional state			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	2	2	3
Conversion disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Delirium			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	2	0	5
Depressed mood			
subjects affected / exposed	6 / 3576 (0.17%)	5 / 3581 (0.14%)	12 / 3576 (0.34%)
occurrences (all)	6	5	12
Depression			
subjects affected / exposed	42 / 3576 (1.17%)	47 / 3581 (1.31%)	93 / 3576 (2.60%)
occurrences (all)	43	47	100
Depressive symptom			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Disorientation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Emotional disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Encopresis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Feelings of worthlessness			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Grief reaction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)



occurrences (all)	1	0	1
Hallucination			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Hallucination, auditory			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Head banging			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Illusion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Initial insomnia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	68 / 3576 (1.90%)	72 / 3581 (2.01%)	101 / 3576 (2.82%)
occurrences (all)	70	75	110
Irritability			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Listless			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Major depression			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	3	0	4
Mental disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Mental fatigue			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Middle insomnia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	1	0	1
Mood altered			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	2
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nervousness			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Neurosis			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	3	2	4
Nicotine dependence			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	3 / 3576 (0.08%)
occurrences (all)	1	0	3
Panic disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Persistent depressive disorder			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Personality change due to a general medical condition			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Post-traumatic stress disorder			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Psychotic disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Psychotic disorder due to a general			

medical condition			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)
occurrences (all)	3	2	3
Schizophreniform disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	7 / 3576 (0.20%)	7 / 3581 (0.20%)	9 / 3576 (0.25%)
occurrences (all)	7	7	9
Somatic symptom disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	6 / 3576 (0.17%)	3 / 3581 (0.08%)	9 / 3576 (0.25%)
occurrences (all)	6	3	9
Tic			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Withdrawal syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Anisomastia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Atrophic vulvovaginitis			
subjects affected / exposed	2 / 3576 (0.06%)	4 / 3581 (0.11%)	4 / 3576 (0.11%)
occurrences (all)	2	4	4
Breast calcifications			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)

occurrences (all)	0	0	0
Breast cyst			
subjects affected / exposed	3 / 3576 (0.08%)	3 / 3581 (0.08%)	5 / 3576 (0.14%)
occurrences (all)	3	3	5
Breast discharge			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Breast disorder			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Breast engorgement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Breast enlargement			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Breast haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Breast mass			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	7 / 3576 (0.20%)
occurrences (all)	3	2	7
Breast pain			
subjects affected / exposed	7 / 3576 (0.20%)	8 / 3581 (0.22%)	12 / 3576 (0.34%)
occurrences (all)	7	9	12
Breast swelling			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Breast ulceration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Cervical dysplasia			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Cervical polyp			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)

occurrences (all)	1	0	1
Cervix inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Colpocele			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Cystocele			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	9 / 3576 (0.25%)
occurrences (all)	4	3	9
Dysfunctional uterine bleeding			
subjects affected / exposed	4 / 3576 (0.11%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)
occurrences (all)	4	1	4
Endometrial hyperplasia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Endometrial hypoplasia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Endometrial thickening			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Fibrocystic breast disease			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Genital atrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Genital haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Genital prolapse			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	4 / 3576 (0.11%)

occurrences (all)	3	1	4
Genital rash			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hydrometra			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Hysterocele			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Mammary duct ectasia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Menopausal symptoms			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Ovarian cyst			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	8 / 3576 (0.22%)
occurrences (all)	2	2	8
Pelvic floor muscle weakness			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pelvic haematoma			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Pelvic pain			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	3	2	5
Perineal pain			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Postmenopausal haemorrhage			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	2	2	5
Pruritus genital			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)

occurrences (all)	1	1	1
Rectocele			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	0	1	2
Urogenital prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Uterine disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Uterine haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Uterine mass			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Uterine polyp			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Uterine prolapse			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	3	2	6
Uterovaginal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Vaginal discharge			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Vaginal haemorrhage			
subjects affected / exposed	8 / 3576 (0.22%)	3 / 3581 (0.08%)	8 / 3576 (0.22%)
occurrences (all)	12	3	12
Vaginal polyp			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vaginal prolapse			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	3 / 3576 (0.08%)

occurrences (all)	0	2	3
Varicocele			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Vulva cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Vulval leukoplakia			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	4 / 3576 (0.11%)	3 / 3581 (0.08%)	6 / 3576 (0.17%)
occurrences (all)	4	3	6
Vulvovaginal pruritus			
subjects affected / exposed	7 / 3576 (0.20%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	7	4	9
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Allergic bronchitis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	3	1
Allergic cough			
subjects affected / exposed	4 / 3576 (0.11%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	4	2	5
Allergic respiratory symptom			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Allergic sinusitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1



Asthma			
subjects affected / exposed	15 / 3576 (0.42%)	22 / 3581 (0.61%)	29 / 3576 (0.81%)
occurrences (all)	17	29	33
Asthmatic crisis			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Atelectasis			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	2	2	5
Bronchial hyperreactivity			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Bronchial obstruction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bronchiectasis			
subjects affected / exposed	2 / 3576 (0.06%)	3 / 3581 (0.08%)	11 / 3576 (0.31%)
occurrences (all)	2	3	11
Bronchitis chronic			
subjects affected / exposed	7 / 3576 (0.20%)	11 / 3581 (0.31%)	15 / 3576 (0.42%)
occurrences (all)	7	12	17
Bronchospasm			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	9 / 3576 (0.25%)
occurrences (all)	2	2	9
Catarrh			
subjects affected / exposed	8 / 3576 (0.22%)	3 / 3581 (0.08%)	13 / 3576 (0.36%)
occurrences (all)	8	3	15
Chronic obstructive pulmonary disease			
subjects affected / exposed	35 / 3576 (0.98%)	29 / 3581 (0.81%)	60 / 3576 (1.68%)
occurrences (all)	40	38	85
Chronic respiratory failure			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	117 / 3576 (3.27%)	130 / 3581 (3.63%)	179 / 3576 (5.01%)
occurrences (all)	128	140	202

Diaphragmatic abnormal relaxation subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Diaphragmatic disorder subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Dry throat subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	0 / 3581 (0.00%) 0	3 / 3576 (0.08%) 3
Dysphonia subjects affected / exposed occurrences (all)	10 / 3576 (0.28%) 10	12 / 3581 (0.34%) 12	10 / 3576 (0.28%) 11
Dyspnoea subjects affected / exposed occurrences (all)	23 / 3576 (0.64%) 24	33 / 3581 (0.92%) 35	36 / 3576 (1.01%) 39
Dyspnoea exertional subjects affected / exposed occurrences (all)	9 / 3576 (0.25%) 9	9 / 3581 (0.25%) 10	12 / 3576 (0.34%) 12
Emphysema subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	3 / 3581 (0.08%) 4	7 / 3576 (0.20%) 7
Epistaxis subjects affected / exposed occurrences (all)	19 / 3576 (0.53%) 22	24 / 3581 (0.67%) 29	26 / 3576 (0.73%) 35
Haemoptysis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	3 / 3576 (0.08%) 3
Haemothorax subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hiccups subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	1 / 3576 (0.03%) 1
Hydrothorax subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1

Hypoventilation			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Hypoxia			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	3
Increased bronchial secretion			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Increased upper airway secretion			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1
Interstitial lung disease			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	1	2	2
Laryngeal disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	3	1	3
Laryngeal inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Laryngitis allergic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Larynx irritation			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Lung consolidation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Lung cyst			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0

Lung disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	1	0	4
Lung infiltration			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Mediastinal disorder			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Mouth breathing			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nasal congestion			
subjects affected / exposed	6 / 3576 (0.17%)	4 / 3581 (0.11%)	9 / 3576 (0.25%)
occurrences (all)	6	4	9
Nasal discomfort			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nasal dryness			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Nasal inflammation			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Nasal mucosal disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nasal mucosal hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Nasal oedema			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0

Nasal polyps			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	0	0	2
Nasal pruritus			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Nasal septum deviation			
subjects affected / exposed	0 / 3576 (0.00%)	3 / 3581 (0.08%)	0 / 3576 (0.00%)
occurrences (all)	0	3	0
Nasal septum perforation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Obstructive airways disorder			
subjects affected / exposed	2 / 3576 (0.06%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	2	1	3
Oropharyngeal discomfort			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	26 / 3576 (0.73%)	26 / 3581 (0.73%)	35 / 3576 (0.98%)
occurrences (all)	27	30	36
Orthopnoea			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pharyngeal inflammation			
subjects affected / exposed	6 / 3576 (0.17%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	6	3	6
Pleural disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1

Pleural effusion			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	3	2	8
Pleural thickening			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Pleurisy			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1
Pneumonia aspiration			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	10 / 3576 (0.28%)	15 / 3581 (0.42%)	14 / 3576 (0.39%)
occurrences (all)	10	15	14
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	1	0	2
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pulmonary calcification			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pulmonary cavitation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pulmonary congestion			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	5 / 3576 (0.14%)
occurrences (all)	2	2	5

Pulmonary embolism			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pulmonary fibrosis			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	0	2	4
Pulmonary granuloma			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	3 / 3576 (0.08%)	9 / 3581 (0.25%)	5 / 3576 (0.14%)
occurrences (all)	3	9	5
Pulmonary infarction			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Pulmonary mass			
subjects affected / exposed	3 / 3576 (0.08%)	1 / 3581 (0.03%)	5 / 3576 (0.14%)
occurrences (all)	3	1	5
Pulmonary oedema			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Pulmonary pain			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	4 / 3576 (0.11%)
occurrences (all)	0	0	4
Reflux laryngitis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Respiratory acidosis			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	1	1	1

Respiratory distress			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	0	1	3
Rhinalgia			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Rhinitis allergic			
subjects affected / exposed	26 / 3576 (0.73%)	23 / 3581 (0.64%)	39 / 3576 (1.09%)
occurrences (all)	26	24	39
Rhinorrhoea			
subjects affected / exposed	6 / 3576 (0.17%)	9 / 3581 (0.25%)	14 / 3576 (0.39%)
occurrences (all)	7	9	15
Sinus congestion			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	3 / 3576 (0.08%)
occurrences (all)	1	1	4
Sinus disorder			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	1 / 3576 (0.03%)
occurrences (all)	0	1	1
Sinus polyp			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sleep apnoea syndrome			
subjects affected / exposed	2 / 3576 (0.06%)	2 / 3581 (0.06%)	4 / 3576 (0.11%)
occurrences (all)	2	2	4
Sneezing			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sputum discoloured			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Sputum retention			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1



Throat irritation			
subjects affected / exposed	1 / 3576 (0.03%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	1	2	1
Throat tightness			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tonsillar inflammation			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	0	0	1
Tonsillolith			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	3 / 3576 (0.08%)	2 / 3581 (0.06%)	6 / 3576 (0.17%)
occurrences (all)	3	2	7
Upper-airway cough syndrome			
subjects affected / exposed	2 / 3576 (0.06%)	0 / 3581 (0.00%)	2 / 3576 (0.06%)
occurrences (all)	2	0	3
Vasomotor rhinitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Vocal cord disorder			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	0 / 3576 (0.00%)
occurrences (all)	0	2	0
Vocal cord thickening			
subjects affected / exposed	0 / 3576 (0.00%)	0 / 3581 (0.00%)	0 / 3576 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	1 / 3576 (0.03%)
occurrences (all)	0	2	1

Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Bile duct obstruction			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Bile duct stone			
subjects affected / exposed	0 / 3576 (0.00%)	2 / 3581 (0.06%)	2 / 3576 (0.06%)
occurrences (all)	0	2	2
Biliary colic			
subjects affected / exposed	3 / 3576 (0.08%)	0 / 3581 (0.00%)	5 / 3576 (0.14%)
occurrences (all)	3	0	5
Biliary cyst			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Biliary dilatation			
subjects affected / exposed	1 / 3576 (0.03%)	1 / 3581 (0.03%)	2 / 3576 (0.06%)
occurrences (all)	1	1	2
Biliary tract disorder			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cholangitis			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cholecystitis			
subjects affected / exposed	1 / 3576 (0.03%)	0 / 3581 (0.00%)	1 / 3576 (0.03%)
occurrences (all)	1	0	1
Cholecystitis chronic			
subjects affected / exposed	0 / 3576 (0.00%)	1 / 3581 (0.03%)	0 / 3576 (0.00%)
occurrences (all)	0	1	0
Cholelithiasis			
subjects affected / exposed	22 / 3576 (0.62%)	20 / 3581 (0.56%)	44 / 3576 (1.23%)
occurrences (all)	22	20	45

Drug-induced liver injury subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Fatty liver alcoholic subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Gallbladder cholesterolosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Gallbladder polyp subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	6 / 3576 (0.17%) 6
Hepatic calcification subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hepatic cirrhosis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0
Hepatic cyst subjects affected / exposed occurrences (all)	18 / 3576 (0.50%) 18	6 / 3581 (0.17%) 6	28 / 3576 (0.78%) 29
Hepatic failure subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hepatic function abnormal subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hepatic lesion subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Hepatic steatosis subjects affected / exposed occurrences (all)	21 / 3576 (0.59%) 25	18 / 3581 (0.50%) 18	35 / 3576 (0.98%) 39
Hepatitis subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1

Hepatobiliary disease subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Hydrocholecystis subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	1 / 3581 (0.03%) 1	0 / 3576 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Hypertransaminaemia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	2 / 3576 (0.06%) 2
Jaundice subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	1 / 3581 (0.03%) 1	2 / 3576 (0.06%) 2
Liver disorder subjects affected / exposed occurrences (all)	2 / 3576 (0.06%) 2	2 / 3581 (0.06%) 2	4 / 3576 (0.11%) 4
Pneumobilia subjects affected / exposed occurrences (all)	1 / 3576 (0.03%) 1	0 / 3581 (0.00%) 0	1 / 3576 (0.03%) 1
Portal hypertension subjects affected / exposed occurrences (all)	0 / 3576 (0.00%) 0	0 / 3581 (0.00%) 0	0 / 3576 (0.00%) 0

<b>Non-serious adverse events</b>	36-Month Study Period: Romosozumab/Deno sumab		
Total subjects affected by non-serious adverse events subjects affected / exposed	3112 / 3581 (86.90%)		
Injury, poisoning and procedural complications Abdominal injury subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		

Accident at work			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Accidental exposure to product			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Anaemia postoperative			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Animal bite			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Animal scratch			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Arthropod bite			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	30		
Arthropod sting			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	11		
Back injury			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Bladder injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bone contusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bone fissure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Brain contusion			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Breast injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Burns first degree			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Burns second degree			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Buttock injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cartilage injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cataract operation complication			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Chemical burn of skin			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chest crushing			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chest injury			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
Clavicle fracture			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Concussion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Conjunctival laceration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Contusion			
subjects affected / exposed	179 / 3581 (5.00%)		
occurrences (all)	212		
Corneal abrasion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Craniocerebral injury			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Crushing injury of trunk			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Deafness traumatic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Epicondylitis			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Eschar			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Excoriation			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
Exposure to communicable disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	3		
Eye burns			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Eye contusion			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Eye injury			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		

Eye operation complication subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Eyelid injury subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Face injury subjects affected / exposed occurrences (all)	9 / 3581 (0.25%) 10		
Facial bones fracture subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Fall subjects affected / exposed occurrences (all)	484 / 3581 (13.52%) 676		
Femoral neck fracture subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Femur fracture subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Fibula fracture subjects affected / exposed occurrences (all)	10 / 3581 (0.28%) 10		
Foot fracture subjects affected / exposed occurrences (all)	22 / 3581 (0.61%) 23		
Foreign body subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Foreign body in eye subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Fracture subjects affected / exposed	0 / 3581 (0.00%)		



occurrences (all)	0		
Fractured ischium			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gingival injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Glaucoma traumatic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Graft complication			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hand fracture			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Head injury			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	24		
Heat exhaustion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Heat illness			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Humerus fracture			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Hypobarism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Iliotibial band syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Incision site pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Incisional hernia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Injury			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	23		
Injury corneal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Joint dislocation			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	18		
Joint injury			
subjects affected / exposed	75 / 3581 (2.09%)		
occurrences (all)	87		
Laceration			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	32		
Ligament injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ligament rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	55 / 3581 (1.54%)		
occurrences (all)	59		
Limb injury			
subjects affected / exposed	106 / 3581 (2.96%)		
occurrences (all)	121		
Lip injury			
subjects affected / exposed	3 / 3581 (0.08%)		

occurrences (all)	3		
Lumbar vertebral fracture			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Mallet finger			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Meniscus injury			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Mouth injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Multiple injuries			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscle injury			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Muscle rupture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	18		
Musculoskeletal injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nail injury			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Nasal injury			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Neck injury			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Nerve injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Overdose			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Patella fracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Perineal injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Periorbital haematoma			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Periorbital haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Perirenal haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peroneal nerve injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural complication			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural contusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural fistula			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Post procedural haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Post procedural haemorrhage subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Post procedural hypothyroidism subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural inflammation subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural swelling subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post-traumatic neck syndrome subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post-traumatic pain subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	11		
Postoperative hernia subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Postoperative ileus subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Postoperative wound complication subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Postpericardiotomy syndrome subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Procedural complication subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Procedural dizziness subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Procedural haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Procedural headache			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	34 / 3581 (0.95%)		
occurrences (all)	36		
Procedural pneumothorax			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pubis fracture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulmonary contusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Radiation associated pain			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Radiation proctitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Radiation skin injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Radius fracture			
subjects affected / exposed	52 / 3581 (1.45%)		
occurrences (all)	53		
Rib fracture			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Road traffic accident			
subjects affected / exposed	16 / 3581 (0.45%)		

occurrences (all)	17		
Scar			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Scratch			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Seroma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Skeletal injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	23 / 3581 (0.64%)		
occurrences (all)	26		
Skin injury			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Skin wound			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Skull fracture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Soft tissue injury			
subjects affected / exposed	32 / 3581 (0.89%)		
occurrences (all)	40		
Spinal column injury			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Spinal compression fracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Spinal fracture			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Splinter			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Stab wound			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sternal fracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sternal injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Subcutaneous haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Subdural haematoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Suture related complication			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Synovial rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tendon injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tendon rupture			
subjects affected / exposed	7 / 3581 (0.20%)		



occurrences (all)	7		
Thermal burn			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Thoracic vertebral fracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Tibia fracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tongue injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	61 / 3581 (1.70%)		
occurrences (all)	71		
Tooth injury			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Toxicity to various agents			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Traumatic haematoma			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Traumatic haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Traumatic lung injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Traumatic ulcer			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ulna fracture			
subjects affected / exposed	15 / 3581 (0.42%)		

occurrences (all)	16		
Ulnar nerve injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vaccination complication			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vascular injury			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	35 / 3581 (0.98%)		
occurrences (all)	38		
Wound secretion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Wrist fracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Investigations			
Abdominal bruit			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Amylase increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Antinuclear antibody increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Aortic bruit			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Arterial bruit			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Arteriogram coronary abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Aspiration bronchial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bacterial test			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Beta 2 microglobulin increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Blood albumin decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Blood bicarbonate decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Blood calcium increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood chloride decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Blood cholesterol increased subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 5		
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Blood folate decreased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Blood glucose abnormal subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Blood glucose increased subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 6		
Blood immunoglobulin G increased subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Blood iron decreased subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Blood iron increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Blood parathyroid hormone increased subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Blood potassium decreased subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Blood potassium increased subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Blood pressure decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	25 / 3581 (0.70%)		
occurrences (all)	25		
Blood pressure systolic increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood sodium decreased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Blood urea increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood uric acid increased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Body height abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Body height decreased			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Body mass index increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Body temperature increased			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Bone density decreased			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Brain scan abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Breath sounds abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
C-reactive protein increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cardiac murmur			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Carotid bruit			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Carotid pulse abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Carotid pulse increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chest X-ray abnormal			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Coagulation time prolonged			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Computerised tomogram head abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Creatinine renal clearance decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Creatinine renal clearance increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Ejection fraction decreased subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Electrocardiogram Q wave abnormal subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Electrocardiogram ST segment elevation subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Electrocardiogram T wave abnormal subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Electrocardiogram abnormal subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Electrocardiogram repolarisation abnormality subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Eosinophil count increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Faecal calprotectin increased subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Fibrin D dimer increased subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 3		
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Glomerular filtration rate abnormal subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Grip strength decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Heart rate increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Heart rate irregular			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Helicobacter test positive			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic enzyme increased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hepatitis A antibody positive			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hepatitis B surface antigen positive			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hepatitis C virus test positive			
subjects affected / exposed	0 / 3581 (0.00%)		



occurrences (all)	0		
Hepatobiliary scan abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Human epidermal growth factor receptor decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intraocular pressure increased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Liver function test abnormal			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Liver function test increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Low density lipoprotein increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lymphocyte count decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lymphocyte morphology abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mammogram abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Monocyte count increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Neutrophil count increased			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Occult blood			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Occult blood positive			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Pancreatic enzymes increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Platelet count decreased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Platelet count increased			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Protein total increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pulmonary arterial pressure increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Reticulocyte count decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Rheumatoid factor positive			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Thyroid function test abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Transaminases increased			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Tuberculin test positive			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ultrasound liver abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urinary system X-ray			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urine output decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Valsalva maneuver			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vitamin B12 increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	54 / 3581 (1.51%)		
occurrences (all)	57		
Weight increased			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
White blood cell count decreased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
White blood cell count increased			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
X-ray abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Angina pectoris			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	20		
Angina unstable			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aortic valve calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Aortic valve disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aortic valve incompetence			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Aortic valve sclerosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Aortic valve stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Arrhythmia			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	17		
Arrhythmia supraventricular			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Atrial fibrillation			
subjects affected / exposed	26 / 3581 (0.73%)		
occurrences (all)	34		
Atrial flutter			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Atrial tachycardia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Atrioventricular block first degree			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Atrioventricular block second degree			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bradycardia			
subjects affected / exposed	20 / 3581 (0.56%)		
occurrences (all)	21		
Bundle branch block left			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Bundle branch block right			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Cardiac aneurysm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cardiac disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Cardiac failure			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	16		
Cardiac failure acute			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Cardiac failure chronic subjects affected / exposed occurrences (all)	9 / 3581 (0.25%) 9		
Cardiac failure congestive subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 5		
Cardiac hypertrophy subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Cardiac septal hypertrophy subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Cardiac valve disease subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 5		
Cardiac valve sclerosis subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Cardiac ventricular disorder subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Cardiomegaly subjects affected / exposed occurrences (all)	11 / 3581 (0.31%) 11		
Cardiomyopathy subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Cardiovascular disorder subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Cardiovascular insufficiency subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Conduction disorder subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		

Congestive cardiomyopathy subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Coronary artery disease subjects affected / exposed occurrences (all)	11 / 3581 (0.31%) 11		
Coronary artery insufficiency subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Coronary artery occlusion subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Cyanosis subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Degenerative aortic valve disease subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Degenerative mitral valve disease subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Diastolic dysfunction subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Dilatation atrial subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 5		
Extrasystoles subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Heart valve calcification subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Heart valve incompetence subjects affected / exposed occurrences (all)	9 / 3581 (0.25%) 10		

Hypertensive cardiomegaly subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Hypertensive cardiomyopathy subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Hypertensive heart disease subjects affected / exposed occurrences (all)	6 / 3581 (0.17%) 6		
Intracardiac thrombus subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Ischaemic cardiomyopathy subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Left atrial dilatation subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Left atrial enlargement subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Left atrial hypertrophy subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Left ventricular dysfunction subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Left ventricular failure subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Left ventricular hypertrophy subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 5		
Low cardiac output syndrome subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		



Mitral valve calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mitral valve disease			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mitral valve incompetence			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	28		
Mitral valve prolapse			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Mitral valve sclerosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Mitral valve stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Myocardial infarction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Myocardial ischaemia			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Palpitations			
subjects affected / exposed	35 / 3581 (0.98%)		
occurrences (all)	36		
Pericardial effusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pericarditis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pulmonary valve incompetence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Right atrial enlargement subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Right ventricular dysfunction subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Right ventricular enlargement subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Right ventricular hypertrophy subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Sinus arrhythmia subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Sinus bradycardia subjects affected / exposed occurrences (all)	7 / 3581 (0.20%) 7		
Sinus node dysfunction subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Sinus tachycardia subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	7 / 3581 (0.20%) 7		
Supraventricular tachycardia subjects affected / exposed occurrences (all)	5 / 3581 (0.14%) 5		
Systolic dysfunction subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Tachyarrhythmia subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		

Tachycardia			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	22		
Tachycardia paroxysmal			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Tricuspid valve incompetence			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	22		
Tricuspid valve stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ventricular arrhythmia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ventricular extrasystoles			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Ventricular hypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ventricular hypokinesia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Congenital, familial and genetic disorders			
Adenomatous polyposis coli			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Arteriovenous malformation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bartter's syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Birth mark			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Congenital cystic kidney disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cortical dysplasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dermoid cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dolichocolon			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Epidermolysis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Extrarenal pelvis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fibrous dysplasia of bone			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder congenital			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intracranial lipoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Polycystic liver disease			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Porokeratosis			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Protein C deficiency			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Renal hypoplasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sacralisation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Spina bifida			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Spine malformation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Syringomyelia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Type IIa hyperlipidaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vertebral artery hypoplasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	99 / 3581 (2.76%)		
occurrences (all)	111		
Anaemia folate deficiency			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Anaemia macrocytic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Anaemia megaloblastic			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bandaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Basophilia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blood disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bone marrow failure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Coagulopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Febrile neutropenia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	5		
Granulocytosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Haemorrhagic anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Hypergammaglobulinaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hyperglobulinaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypochromic anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Increased tendency to bruise			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Iron deficiency anaemia			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	26		
Leukocytosis			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Leukopenia			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	27		
Lymph node calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lymph node pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lymphadenitis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Lymphadenopathy			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	9		

Lymphocytosis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Lymphopenia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Microcytic anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Nephrogenic anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	22		
Neutrophilia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Normochromic normocytic anaemia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Pancytopenia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Polycythaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sideroblastic anaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Splenomegaly			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		



Thrombocytosis subjects affected / exposed occurrences (all)	9 / 3581 (0.25%) 9		
Nervous system disorders			
Acoustic neuritis subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Akathisia subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Amnesia subjects affected / exposed occurrences (all)	15 / 3581 (0.42%) 15		
Aphonia subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Arachnoid cyst subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Autonomic nervous system imbalance subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Balance disorder subjects affected / exposed occurrences (all)	13 / 3581 (0.36%) 14		
Brain injury subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Burning feet syndrome subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Burning sensation subjects affected / exposed	13 / 3581 (0.36%)		

occurrences (all)	14		
Carotid arteriosclerosis			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Carotid artery disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Carotid artery stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Carpal tunnel syndrome			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	18		
Central nervous system lesion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cerebellar atrophy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cerebellar syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cerebral arteriosclerosis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Cerebral artery stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cerebral atrophy			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Cerebral calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cerebral disorder			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Cerebral haematoma			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cerebral haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cerebral infarction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cerebral ischaemia			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Cerebral microangiopathy			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Cerebroscclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cerebrovascular accident			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cerebrovascular disorder			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cervical myelopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cervical radiculopathy			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Cervicobrachial syndrome			
subjects affected / exposed	5 / 3581 (0.14%)		

occurrences (all)	5		
Cognitive disorder			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Complex regional pain syndrome			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cranial nerve disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dementia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Dementia Alzheimer's type			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Demyelination			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Diabetic neuropathy			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Dizziness			
subjects affected / exposed	228 / 3581 (6.37%)		
occurrences (all)	264		
Dizziness exertional			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dizziness postural			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Drooling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Drug withdrawal headache			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Dysarthria			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	8		
Dyskinesia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dysphonia psychogenic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Encephalopathy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Epilepsy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Essential tremor			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Extrapyramidal disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Facial neuralgia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Facial paralysis			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Haemorrhagic stroke			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Head discomfort			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	293 / 3581 (8.18%)		
occurrences (all)	352		
Hemianopia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hemianopia heteronymous			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hemiparesis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hydrocephalus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hyperaesthesia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypersomnia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	48 / 3581 (1.34%)		
occurrences (all)	57		
Hyposmia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Intercostal neuralgia			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Intracranial aneurysm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ischaemic stroke			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lacunar infarction			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Lethargy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Leukoencephalomyelitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Leukoencephalopathy			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Loss of consciousness			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Lumbar radiculopathy			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	14		
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	26 / 3581 (0.73%)		
occurrences (all)	27		
Migraine			
subjects affected / exposed	16 / 3581 (0.45%)		

occurrences (all)	17		
Migraine with aura			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Mononeuropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Monoparesis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Morton's neuralgia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Movement disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Multiple sclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Multiple sclerosis relapse			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscle contractions involuntary			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Myasthenia gravis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nerve compression			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Nerve root compression			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Nervous system disorder			
subjects affected / exposed	1 / 3581 (0.03%)		



occurrences (all)	1		
Neuralgia			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Neuritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Neuropathy peripheral			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Noninfective encephalitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Occipital neuralgia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Optic neuritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Osmotic demyelination syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	87 / 3581 (2.43%)		
occurrences (all)	101		
Paraparesis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Parkinson's disease			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Parkinsonism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Parosmia			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Peripheral motor neuropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral nerve palsy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peripheral nerve paresis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Polyneuropathy			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Poor quality sleep			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Post herpetic neuralgia			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Post polio syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post-traumatic epilepsy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Post-traumatic headache			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Precerebral arteriosclerosis			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Presyncope			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Pseudoradicular syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Psychomotor hyperactivity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Radicular pain			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Radicular syndrome			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Radiculopathy			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	11		
Restless legs syndrome			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	7		
Sciatic nerve neuropathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	94 / 3581 (2.62%)		
occurrences (all)	110		
Sedation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Senile dementia			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Sinus headache			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Speech disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Spinal cord disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Spinal meningeal cyst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	41 / 3581 (1.14%)		
occurrences (all)	44		
Tarsal tunnel syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tension headache			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	18		
Tongue biting			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Transient ischaemic attack			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Tremor			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	20		
Trigeminal nerve paresis			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Trigeminal neuralgia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Trigeminal neuritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Unresponsive to stimuli			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vlth nerve paralysis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vascular dementia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vascular encephalopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vertebrobasilar insufficiency			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Vertigo CNS origin			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Visual field defect			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Vocal cord paralysis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
White matter lesion			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Eye disorders			

Age-related macular degeneration			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Amaurosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Amblyopia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Angle closure glaucoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Arteriosclerotic retinopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Asthenopia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Astigmatism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blepharitis			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Blepharitis allergic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blepharochalasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blindness transient			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Blindness unilateral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Cataract			
subjects affected / exposed	152 / 3581 (4.24%)		
occurrences (all)	191		
Cataract diabetic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cataract nuclear			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chalazion			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Chorioretinopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	5		
Conjunctival haemorrhage			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	20		
Conjunctival hyperaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Conjunctival irritation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Conjunctival ulcer			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Conjunctivitis allergic			
subjects affected / exposed	23 / 3581 (0.64%)		
occurrences (all)	23		
Conjunctivochalasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Corneal degeneration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Corneal leukoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dacryostenosis acquired			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Diabetic retinopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Diplopia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Dry age-related macular degeneration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	24		
Ectropion			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Entropion			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Erythema of eyelid			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Exfoliation glaucoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Exophthalmos			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eye allergy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		



Eye discharge			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eye disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eye haemorrhage			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Eye inflammation			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Eye irritation			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Eye movement disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	12		
Eye pruritus			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Eye swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eyelid disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eyelid haematoma			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Eyelid oedema			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		

Eyelid ptosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Eyelid rash			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eyelids pruritus			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Foreign body sensation in eyes			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Glaucoma			
subjects affected / exposed	40 / 3581 (1.12%)		
occurrences (all)	42		
Hypermetropia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Keratitis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Keratopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lacrimal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lacrimation increased			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
Lenticular opacities			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Macular degeneration			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Macular fibrosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Macular hole			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Macular oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Maculopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Meibomian gland dysfunction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mydriasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Neovascular age-related macular degeneration			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ocular discomfort			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ocular hyperaemia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Open angle glaucoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Photopsia			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Posterior capsule opacification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Presbyopia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Pterygium			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Refraction disorder			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Retinal degeneration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Retinal detachment			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Retinal disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Retinal dystrophy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Retinal haemorrhage			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Retinal tear			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Retinal vascular disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Retinal vascular thrombosis			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Retinal vein occlusion			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Retinal vein thrombosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Retinopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Retinopathy hypertensive			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Scleral haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Strabismus			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Sudden visual loss			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Trichiasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Uveitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Visual acuity reduced			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Visual acuity reduced transiently			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Visual impairment			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Vitreous degeneration			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Vitreous detachment			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Vitreous disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Vitreous haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Xerophthalmia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Auditory disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cerumen impaction			
subjects affected / exposed	20 / 3581 (0.56%)		
occurrences (all)	20		
Conductive deafness			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Deafness			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Deafness bilateral			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Deafness neurosensory			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Deafness unilateral			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Dysacusis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ear congestion			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Ear discomfort			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ear disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ear pain			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	23		
Ear pruritus			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Excessive cerumen production			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
External ear disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
External ear inflammation			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hypoacusis			
subjects affected / exposed	21 / 3581 (0.59%)		
occurrences (all)	21		
Inner ear disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Meniere's disease			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	6		
Middle ear effusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Middle ear inflammation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mixed deafness			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Motion sickness			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Neurosensory hypoacusis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Otorrhoea			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Otosclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Presbycusis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sudden hearing loss			



subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Tinnitus			
subjects affected / exposed	38 / 3581 (1.06%)		
occurrences (all)	39		
Tympanic membrane disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Tympanosclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	113 / 3581 (3.16%)		
occurrences (all)	133		
Vertigo labyrinthine			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vertigo positional			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Vestibular ataxia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vestibular disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Abdominal discomfort			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		

Abdominal distension			
subjects affected / exposed	40 / 3581 (1.12%)		
occurrences (all)	44		
Abdominal hernia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abdominal mass			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	89 / 3581 (2.49%)		
occurrences (all)	107		
Abdominal pain lower			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Abdominal pain upper			
subjects affected / exposed	123 / 3581 (3.43%)		
occurrences (all)	135		
Abdominal tenderness			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Abnormal faeces			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Acid peptic disease			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Amalgam tattoo			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anal fissure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Anal fistula			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anal haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anal incontinence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anal prolapse			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Anal pruritus			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Anorectal discomfort			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anorectal disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Anorectal varices			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aphthous ulcer			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	11		
Ascites			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Barrett's oesophagus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bowel movement irregularity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Breath odour			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Change of bowel habit			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cheilitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chronic gastritis			
subjects affected / exposed	37 / 3581 (1.03%)		
occurrences (all)	39		
Coeliac disease			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Colitis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Colitis ischaemic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Colitis microscopic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Colitis psychogenic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Colitis ulcerative			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Colon dysplasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	189 / 3581 (5.28%)		
occurrences (all)	216		

Crohn's disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dental caries			
subjects affected / exposed	120 / 3581 (3.35%)		
occurrences (all)	144		
Dental cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dental necrosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Diaphragmatic hernia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	182 / 3581 (5.08%)		
occurrences (all)	217		
Diarrhoea haemorrhagic			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Diverticulum			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	18		
Diverticulum intestinal			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	25		
Diverticulum oesophageal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	30		
Duodenal polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Duodenal ulcer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Duodenitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Duodenogastric reflux			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Dyspepsia			
subjects affected / exposed	122 / 3581 (3.41%)		
occurrences (all)	136		
Dysphagia			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	7		
Enamel anomaly			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Enteritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Enterocolitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Epigastric discomfort			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Erosive duodenitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Erosive oesophagitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Eructation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		

Faeces discoloured			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Faeces hard			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Faeces pale			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Femoral hernia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	16		
Food poisoning			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Frequent bowel movements			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastric disorder			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Gastric mucosa erythema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastric mucosal hypertrophy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Gastric polyps			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Gastric ulcer			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Gastric xanthoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	142 / 3581 (3.97%)		
occurrences (all)	174		
Gastritis erosive			
subjects affected / exposed	19 / 3581 (0.53%)		
occurrences (all)	19		
Gastritis haemorrhagic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastroduodenal ulcer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastroduodenitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Gastrointestinal haemorrhage			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Gastrointestinal inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		



Gastrointestinal mucosal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastrointestinal necrosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal pain			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Gastrointestinal sounds abnormal			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Gastrooesophageal reflux disease			
subjects affected / exposed	78 / 3581 (2.18%)		
occurrences (all)	84		
Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gingival bleeding			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Gingival disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Gingival erosion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gingival erythema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gingival hypertrophy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gingival pain			
subjects affected / exposed	14 / 3581 (0.39%)		

occurrences (all)	15		
Gingival recession			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gingival swelling			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Gingival ulceration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Glossitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Glossodynia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Haematemesis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Haematochezia			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Haemorrhoids			
subjects affected / exposed	44 / 3581 (1.23%)		
occurrences (all)	44		
Hiatus hernia			
subjects affected / exposed	35 / 3581 (0.98%)		
occurrences (all)	35		
Hyperchlorhydria			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Ileal ulcer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ileus			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Impaired gastric emptying			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Inflammatory bowel disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Inguinal hernia			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Intestinal haemorrhage			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Intestinal metaplasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Intestinal obstruction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intestinal polyp			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Intra-abdominal haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Intussusception			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Irritable bowel syndrome			
subjects affected / exposed	45 / 3581 (1.26%)		

occurrences (all)	50		
Large intestinal stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Large intestinal ulcer			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Large intestine polyp			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	24		
Leukoplakia oral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lip haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lip ulceration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Loose tooth			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	31		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lumbar hernia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Megacolon			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Melaena			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mouth cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mouth swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Mucous stools			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	65 / 3581 (1.82%)		
occurrences (all)	72		
Noninfective gingivitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Odynophagia			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Oesophageal achalasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oesophageal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oesophageal motility disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oesophageal stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Oesophagitis			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Oral cavity fistula			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral contusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral discomfort			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Oral lichen planus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral mucosa erosion			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Oral mucosal blistering			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pancreatic cyst			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	7		
Pancreatic disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pancreatic duct dilatation			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Pancreatic fistula			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pancreatic pseudocyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pancreatic steatosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pancreatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pancreatitis acute			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pancreatitis chronic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Paraesthesia oral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Parotid gland enlargement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peptic ulcer			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Periodontal disease			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Periodontal inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Peritoneal lesion			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Portal hypertensive gastropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Proctalgia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Proctitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rectal haemorrhage			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Rectal polyp			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Rectal prolapse			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rectal tenesmus			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Reflux gastritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Regurgitation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Salivary duct obstruction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Salivary gland enlargement			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Salivary hypersecretion			
subjects affected / exposed	2 / 3581 (0.06%)		



occurrences (all)	2		
Sciatic hernia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sensitivity of teeth			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Stomatitis			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	14		
Submaxillary gland enlargement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Swollen tongue			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tongue blistering			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tongue discolouration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tongue disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tongue haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Tongue ulceration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tooth deposit			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tooth discolouration			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Tooth disorder			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Tooth loss			
subjects affected / exposed	47 / 3581 (1.31%)		
occurrences (all)	53		
Toothache			
subjects affected / exposed	49 / 3581 (1.37%)		
occurrences (all)	56		
Umbilical hernia			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Varices oesophageal			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	70 / 3581 (1.95%)		
occurrences (all)	76		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Azotaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bladder disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bladder diverticulum			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bladder dysfunction			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bladder pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bladder prolapse			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Bladder spasm			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Calculus bladder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Calculus urinary			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Choluria			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chromaturia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Chronic kidney disease			
subjects affected / exposed	34 / 3581 (0.95%)		
occurrences (all)	36		
Cystitis haemorrhagic			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Cystitis interstitial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cystitis noninfective			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Diabetic nephropathy			

subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Dysuria			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	27		
Haematuria			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	14		
Hydrocalyx			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Hypercalciuria			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypertensive nephropathy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hypertonic bladder			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Incontinence			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Kidney enlargement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Kidney fibrosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Leukocyturia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Microalbuminuria			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Micturition disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Nephrocalcinosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nephrolithiasis			
subjects affected / exposed	33 / 3581 (0.92%)		
occurrences (all)	33		
Nephropathy			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Nephrosclerosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Neurogenic bladder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nocturia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Pollakiuria			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	11		
Polyuria			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Proteinuria			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pyelocaliectasis			

subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Renal artery stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Renal atrophy			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Renal colic			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Renal cyst			
subjects affected / exposed	44 / 3581 (1.23%)		
occurrences (all)	46		
Renal disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Renal failure			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Renal impairment			
subjects affected / exposed	23 / 3581 (0.64%)		
occurrences (all)	24		
Renal lipomatosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Renal mass			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Renal pain			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Stress urinary incontinence			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ureteric dilatation			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ureteric stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ureterolithiasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urethral caruncle			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urethral pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urethral stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urethral syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urge incontinence			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Urinary hesitation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	29 / 3581 (0.81%)		
occurrences (all)	30		
Urinary retention			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Urinary tract disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urinary tract inflammation			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urine flow decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urine odour abnormal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urogenital haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Product issues			
Device breakage			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Device dislocation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Device extrusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Device failure			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	10		
Device loosening			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Device malfunction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Actinic keratosis			
subjects affected / exposed	10 / 3581 (0.28%)		



occurrences (all)	10		
Alopecia			
subjects affected / exposed	36 / 3581 (1.01%)		
occurrences (all)	38		
Alopecia areata			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Angiodermatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Angioedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Asteatosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Blister			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Blister rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chronic pigmented purpura			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cutis laxa			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dandruff			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Dermal cyst			
subjects affected / exposed	9 / 3581 (0.25%)		

occurrences (all)	10		
Dermatitis			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	30		
Dermatitis acneiform			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dermatitis allergic			
subjects affected / exposed	40 / 3581 (1.12%)		
occurrences (all)	45		
Dermatitis atopic			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Dermatitis bullous			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	19		
Diabetic dermopathy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Diabetic foot			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Drug eruption			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Dry skin			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Dyshidrotic eczema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ecchymosis			
subjects affected / exposed	38 / 3581 (1.06%)		

occurrences (all)	41		
Eczema			
subjects affected / exposed	46 / 3581 (1.28%)		
occurrences (all)	51		
Eczema asteatotic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	33		
Erythema multiforme			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Exfoliative rash			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Generalised erythema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Granuloma annulare			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	5		
Haemorrhage subcutaneous			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hand dermatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hirsutism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Hyperkeratosis			
subjects affected / exposed	11 / 3581 (0.31%)		

occurrences (all)	11		
Hypertrophic scar			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Idiopathic urticaria			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ingrowing nail			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Intertrigo			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Leukoplakia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lichen planus			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Lichen sclerosus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lipohypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Macule			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Mechanical urticaria			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Miliaria			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Nail bed disorder			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Nail bed inflammation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nail discolouration			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Nail disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Nail hypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nail psoriasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nail ridging			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Neurodermatitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Onychoclasia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Onycholysis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Onychomadesis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Onychomalacia			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Pain of skin			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Palmoplantar keratoderma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Panniculitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Papule			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Peau d'orange			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Photosensitivity reaction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pigmentation disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pityriasis rosea			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	54 / 3581 (1.51%)		
occurrences (all)	63		
Pruritus allergic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pruritus generalised			
subjects affected / exposed	22 / 3581 (0.61%)		

occurrences (all)	25		
Psoriasis			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	11		
Purpura			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	57 / 3581 (1.59%)		
occurrences (all)	68		
Rash erythematous			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Rash generalised			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Rash macular			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Rash maculo-papular			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rash papular			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Rash pruritic			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	19		
Rosacea			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Scab			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Scar pain			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Seborrhoeic dermatitis			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	10		
Skin atrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin burning sensation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Skin discolouration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Skin disorder			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Skin erosion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin exfoliation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin fissures			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Skin haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin hyperpigmentation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin hypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Skin induration			
subjects affected / exposed	1 / 3581 (0.03%)		



occurrences (all)	1		
Skin irritation			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Skin lesion			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	23		
Skin mass			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin plaque			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin swelling			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Skin ulcer			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Skin ulcer haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin warm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Solar dermatitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Solar lentigo			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Stasis dermatitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Subcutaneous emphysema			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Sweat gland disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Swelling face			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Telangiectasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Trichorrhexis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	27 / 3581 (0.75%)		
occurrences (all)	33		
Urticaria chronic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vascular purpura			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vascular skin disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vitiligo			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Xeroderma			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Musculoskeletal and connective tissue disorders			

Ankle deformity				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences (all)	0			
Arthralgia				
subjects affected / exposed	668 / 3581 (18.65%)			
occurrences (all)	928			
Arthritis				
subjects affected / exposed	30 / 3581 (0.84%)			
occurrences (all)	31			
Arthritis reactive				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences (all)	1			
Arthropathy				
subjects affected / exposed	4 / 3581 (0.11%)			
occurrences (all)	4			
Back pain				
subjects affected / exposed	518 / 3581 (14.47%)			
occurrences (all)	649			
Bone atrophy				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences (all)	0			
Bone cyst				
subjects affected / exposed	1 / 3581 (0.03%)			
occurrences (all)	1			
Bone deformity				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences (all)	0			
Bone disorder				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences (all)	2			
Bone infarction				
subjects affected / exposed	0 / 3581 (0.00%)			
occurrences (all)	0			
Bone loss				
subjects affected / exposed	2 / 3581 (0.06%)			
occurrences (all)	2			

Bone pain			
subjects affected / exposed	72 / 3581 (2.01%)		
occurrences (all)	87		
Bursitis			
subjects affected / exposed	33 / 3581 (0.92%)		
occurrences (all)	36		
Cervical spinal stenosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Chondritis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chondrocalcinosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chondrolysis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chondromalacia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chondropathy			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Coccydynia			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Costochondritis			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	17		
Crystal arthropathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Deformity thorax			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dupuytren's contracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Enthesopathy			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Exostosis			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	20		
Extremity contracture			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Facial asymmetry			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Fasciitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Fibromyalgia			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Finger deformity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fistula			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Foot deformity			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	15		

Fracture delayed union			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fracture pain			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Gouty arthritis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	19 / 3581 (0.53%)		
occurrences (all)	19		
Interspinous osteoarthritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Intervertebral disc compression			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Intervertebral disc degeneration			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Intervertebral disc disorder			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	28		
Intervertebral disc displacement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intervertebral disc protrusion			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	17		
Intervertebral disc space narrowing			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Jaw cyst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Joint contracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Joint crepitation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Joint effusion			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Joint hyperextension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Joint lock			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Joint range of motion decreased			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Joint stiffness			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Joint swelling			
subjects affected / exposed	26 / 3581 (0.73%)		
occurrences (all)	28		
Joint warmth			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Kyphosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ligamentitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Limb asymmetry			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Limb discomfort			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Limb mass			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lordosis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Low turnover osteopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lumbar spinal stenosis			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Mastication disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Meniscal degeneration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Metatarsalgia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Mobility decreased			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Monarthrititis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Muscle atrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscle contracture			
subjects affected / exposed	25 / 3581 (0.70%)		
occurrences (all)	27		



Muscle fatigue			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Muscle haemorrhage			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	211 / 3581 (5.89%)		
occurrences (all)	246		
Muscle tightness			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscle twitching			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	29 / 3581 (0.81%)		
occurrences (all)	31		
Musculoskeletal chest pain			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	29		
Musculoskeletal discomfort			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Musculoskeletal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	263 / 3581 (7.34%)		
occurrences (all)	304		
Musculoskeletal stiffness			
subjects affected / exposed	20 / 3581 (0.56%)		
occurrences (all)	22		
Myalgia			
subjects affected / exposed	159 / 3581 (4.44%)		
occurrences (all)	181		

Myofascial pain syndrome			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	5		
Myofascitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Myositis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Myositis ossificans			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Neck deformity			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	116 / 3581 (3.24%)		
occurrences (all)	127		
Nodal osteoarthritis			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Osteitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Osteoarthritis			
subjects affected / exposed	321 / 3581 (8.96%)		
occurrences (all)	398		
Osteochondritis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Osteochondrosis			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Osteolysis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Osteonecrosis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Osteopenia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Osteosclerosis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	8		
Pain in extremity			
subjects affected / exposed	417 / 3581 (11.64%)		
occurrences (all)	536		
Pain in jaw			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Palindromic rheumatism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Patellofemoral pain syndrome			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Periarthritis			
subjects affected / exposed	25 / 3581 (0.70%)		
occurrences (all)	27		
Periostitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Peripheral arthritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Plantar fasciitis			
subjects affected / exposed	18 / 3581 (0.50%)		

occurrences (all)	18		
Polyarthrititis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Polymyalgia rheumatica			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Rheumatic disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rheumatoid arthritis			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Rib deformity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rotator cuff syndrome			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	18		
Sacroiliitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Sarcopenia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Scoliosis			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	18		
Senile ankylosing vertebral hyperostosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Seronegative arthritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sinus tarsi syndrome			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sjogren's syndrome			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Spinal column stenosis			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Spinal deformity			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Spinal disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Spinal flattening			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Spinal osteoarthritis			
subjects affected / exposed	137 / 3581 (3.83%)		
occurrences (all)	188		
Spinal pain			
subjects affected / exposed	62 / 3581 (1.73%)		
occurrences (all)	68		
Spondylitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Spondylolisthesis			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	16		
Spondylolysis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sympathetic posterior cervical syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Synovial cyst			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	29		
Synovitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Systemic lupus erythematosus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Temporomandibular joint syndrome			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Tendinous contracture			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tendon disorder			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Tendon pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	44 / 3581 (1.23%)		
occurrences (all)	45		
Tenosynovitis			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	18		
Tenosynovitis stenosans			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Torticollis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Trigger finger			
subjects affected / exposed	25 / 3581 (0.70%)		
occurrences (all)	27		

Vertebral foraminal stenosis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vertebral osteophyte subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Vertebral wedging subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Wrist deformity subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Endocrine disorders			
Adrenal disorder subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Adrenal insufficiency subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Adrenal mass subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	6 / 3581 (0.17%) 6		
Endocrine disorder subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Goitre subjects affected / exposed occurrences (all)	33 / 3581 (0.92%) 34		
Haemorrhagic thyroid cyst subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Hyperparathyroidism subjects affected / exposed	4 / 3581 (0.11%)		

occurrences (all)	4		
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hyperthyroidism			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Hypoparathyroidism			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypothyroidic goitre			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	79 / 3581 (2.21%)		
occurrences (all)	81		
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Myxoedema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Primary hypothyroidism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Secondary hypothyroidism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroid atrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroid cyst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroid disorder			



subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroid mass			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	10		
Thyroiditis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Thyroiditis chronic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroiditis subacute			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Acquired mixed hyperlipidaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cachexia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Calcium metabolism disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Carbohydrate intolerance			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Central obesity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cow's milk intolerance			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Decreased appetite			
subjects affected / exposed	42 / 3581 (1.17%)		
occurrences (all)	44		
Dehydration			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Diabetes mellitus			
subjects affected / exposed	57 / 3581 (1.59%)		
occurrences (all)	63		
Diabetes mellitus inadequate control			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dyslipidaemia			
subjects affected / exposed	134 / 3581 (3.74%)		
occurrences (all)	136		
Electrolyte imbalance			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Fluid overload			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fluid retention			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Folate deficiency			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Food intolerance			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Glucose tolerance impaired			
subjects affected / exposed	27 / 3581 (0.75%)		
occurrences (all)	27		

Gout			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	7		
Hyper HDL cholesterolaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hyperammonaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypercalcaemia			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Hyperchloraemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypercholesterolaemia			
subjects affected / exposed	85 / 3581 (2.37%)		
occurrences (all)	87		
Hyperglycaemia			
subjects affected / exposed	50 / 3581 (1.40%)		
occurrences (all)	56		
Hyperkalaemia			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Hyperlipidaemia			
subjects affected / exposed	26 / 3581 (0.73%)		
occurrences (all)	26		
Hypermagnesaemia			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Hypernatraemia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Hyperproteinaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Hypertriglyceridaemia			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	22		
Hyperuricaemia			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	19		
Hypervitaminosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Hypochloraemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	19 / 3581 (0.53%)		
occurrences (all)	24		
Hypokalaemia			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	31		
Hypomagnesaemia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Hyponatraemia			
subjects affected / exposed	24 / 3581 (0.67%)		
occurrences (all)	27		
Hypophosphataemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypoproteinaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Hypovolaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Impaired fasting glucose			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Increased appetite			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Insulin resistance			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Lactose intolerance			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Latent tetany			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lipid metabolism disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Malnutrition			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Metabolic disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Metabolic syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Obesity			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		

Overweight			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Periarthritis calcarea			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Plasma protein metabolism disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Polydipsia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Type 2 diabetes mellitus			
subjects affected / exposed	34 / 3581 (0.95%)		
occurrences (all)	37		
Underweight			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vitamin B complex deficiency			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Vitamin B12 deficiency			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	11		
Vitamin D deficiency			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abscess			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Abscess bacterial			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Abscess jaw			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abscess limb			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Abscess neck			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abscess of eyelid			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abscess oral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Abscess rupture			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Actinomycotic pulmonary infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Acute sinusitis			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	12		
Alphaviral infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Amoebiasis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Amoebic dysentery			
subjects affected / exposed	6 / 3581 (0.17%)		

occurrences (all)	6		
Anal abscess			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Angular cheilitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Appendicitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Arthritis bacterial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ascariasis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Asymptomatic bacteriuria			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Atypical pneumonia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bacteraemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bacterial diarrhoea			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Bacterial infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bacterial rhinitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bacterial vaginosis			
subjects affected / exposed	9 / 3581 (0.25%)		



occurrences (all)	9		
Bacteriuria			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Blastocystis infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Body tinea			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Borrelia infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Bronchiolitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Bronchitis			
subjects affected / exposed	173 / 3581 (4.83%)		
occurrences (all)	205		
Bronchitis bacterial			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	17		
Bronchitis viral			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Candida infection			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cellulitis			
subjects affected / exposed	27 / 3581 (0.75%)		
occurrences (all)	30		
Chikungunya virus infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cholecystitis infective			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chronic hepatitis C			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chronic sinusitis			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	7		
Chronic tonsillitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Clostridial infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Clostridium difficile infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	54 / 3581 (1.51%)		
occurrences (all)	57		
Conjunctivitis bacterial			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Conjunctivitis viral			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Cystitis			

subjects affected / exposed	84 / 3581 (2.35%)		
occurrences (all)	100		
Cystitis bacterial			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	19		
Cystitis escherichia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cystitis klebsiella			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cystitis viral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dacryocystitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dengue fever			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Dental fistula			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dental gangrene			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dermatitis infected			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dermatophytosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dermatophytosis of nail			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Diarrhoea infectious			

subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Diverticulitis			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Dysentery			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	18		
Ear infection bacterial			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ear infection viral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eczema impetiginous			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eczema infected			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Enteritis infectious			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Enterobiasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Enterocolitis infectious			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Erysipelas			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	10		
Erythema migrans			

subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Escherichia urinary tract infection			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Eye infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Eye infection bacterial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Eyelid infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Flavivirus infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	8		
Fungal infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Fungal skin infection			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Furuncle			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Gastric infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastric ulcer helicobacter			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastritis viral			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	99 / 3581 (2.76%)		
occurrences (all)	107		
Gastroenteritis bacterial			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	63 / 3581 (1.76%)		
occurrences (all)	65		
Gastrointestinal bacterial infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastrointestinal candidiasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal infection			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Gastrointestinal viral infection			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Genital herpes			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Genital infection fungal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Giardiasis			

subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Gingival abscess			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	38 / 3581 (1.06%)		
occurrences (all)	38		
Groin abscess			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Haemophilus infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Helicobacter gastritis			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Helicobacter infection			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	22		
Helminthic infection			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Hepatitis B			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatitis C			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatitis viral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Herpes dermatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Herpes ophthalmic			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Herpes virus infection			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	5		
Herpes zoster			
subjects affected / exposed	72 / 3581 (2.01%)		
occurrences (all)	73		
Herpes zoster infection neurological			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Herpes zoster oticus			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hookworm infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hordeolum			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Impetigo			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Incision site infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Infected bite			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Infected cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Infected dermal cyst			



subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Infected skin ulcer			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Infection			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Infection parasitic			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Infective exacerbation of bronchiectasis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	237 / 3581 (6.62%)		
occurrences (all)	292		
Injection site infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Kaposi's varicelliform eruption			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Keratitis viral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Labyrinthitis			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	19		
Laryngitis			
subjects affected / exposed	29 / 3581 (0.81%)		
occurrences (all)	32		

Laryngitis bacterial			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Laryngitis viral			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Latent syphilis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Localised infection			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Lower respiratory tract infection			
subjects affected / exposed	31 / 3581 (0.87%)		
occurrences (all)	40		
Lower respiratory tract infection bacterial			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lung infection			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Lyme disease			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Malaria			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mastitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mastitis bacterial			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Mastoiditis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mumps			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mycobacterial infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mycobacterium avium complex infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Myringitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nail bed infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nail bed infection bacterial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nail infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nasal abscess			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	651 / 3581 (18.18%)		
occurrences (all)	921		
Nematodiasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Oesophageal candidiasis			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Onychomycosis			
subjects affected / exposed	26 / 3581 (0.73%)		
occurrences (all)	28		
Oral bacterial infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Oral fungal infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	31 / 3581 (0.87%)		
occurrences (all)	32		
Oral infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral viral infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oropharyngeal candidiasis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Osteomyelitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Osteomyelitis chronic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Otitis externa			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Otitis externa bacterial			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Otitis media			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Otitis media acute			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Otitis media bacterial			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Otitis media chronic			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Otosalpingitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Parasitic gastroenteritis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Paronychia			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Parotitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pelvic inflammatory disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peptic ulcer helicobacter			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Perichondritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pericoronitis			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Periodontitis			
subjects affected / exposed	37 / 3581 (1.03%)		
occurrences (all)	40		
Periorbital cellulitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peritonsillar abscess			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pharyngitis			
subjects affected / exposed	69 / 3581 (1.93%)		
occurrences (all)	77		
Pharyngitis bacterial			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Pharyngitis streptococcal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pharyngotonsillitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Pilonidal cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	64 / 3581 (1.79%)		
occurrences (all)	72		
Pneumonia adenoviral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pneumonia bacterial			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	8		
Pneumonia cryptococcal			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pneumonia viral			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post procedural infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post viral fatigue syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Postoperative wound infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pulmonary tuberculosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulpitis dental			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Pyelonephritis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Pyelonephritis acute			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pyelonephritis chronic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pyuria			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rash pustular			

subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Respiratory tract infection			
subjects affected / exposed	39 / 3581 (1.09%)		
occurrences (all)	41		
Respiratory tract infection bacterial			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Respiratory tract infection viral			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	12		
Rhinitis			
subjects affected / exposed	59 / 3581 (1.65%)		
occurrences (all)	66		
Root canal infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rotavirus infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sialoadenitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sinobronchitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	80 / 3581 (2.23%)		
occurrences (all)	88		
Sinusitis bacterial			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Skin bacterial infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin candida			



subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Soft tissue infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Staphylococcal infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Staphylococcal skin infection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Stoma site abscess			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Streptococcal infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Streptococcal urinary tract infection			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Subcutaneous abscess			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	8		
Superinfection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Superinfection bacterial			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Tick-borne viral encephalitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tinea capitis			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tinea cruris			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tinea infection			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Tinea pedis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Tinea versicolour			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	22		
Tonsillitis bacterial			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	9		
Tooth abscess			
subjects affected / exposed	25 / 3581 (0.70%)		
occurrences (all)	26		
Tooth infection			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	24		
Tracheitis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Tracheobronchitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Trichuriasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tuberculosis			

subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	236 / 3581 (6.59%)		
occurrences (all)	414		
Upper respiratory tract infection bacterial			
subjects affected / exposed	20 / 3581 (0.56%)		
occurrences (all)	21		
Urethritis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	244 / 3581 (6.81%)		
occurrences (all)	296		
Urinary tract infection bacterial			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	34		
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Urinary tract infection viral			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vaginal cellulitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vaginal infection			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Vaginitis bacterial			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		

Varicella			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Viraemia			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Viral diarrhoea			
subjects affected / exposed	27 / 3581 (0.75%)		
occurrences (all)	28		
Viral hepatitis carrier			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	50 / 3581 (1.40%)		
occurrences (all)	53		
Viral labyrinthitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Viral pharyngitis			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Viral rash			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Viral rhinitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Viral sinusitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Viral skin infection			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	230 / 3581 (6.42%)		
occurrences (all)	352		

Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 5		
Vulvovaginitis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Wound infection subjects affected / exposed occurrences (all)	9 / 3581 (0.25%) 9		
Wound infection bacterial subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Zika virus infection subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vascular disorders			
Aneurysm subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Angiosclerosis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Aortic aneurysm subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	21 / 3581 (0.59%) 22		
Aortic calcification subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Aortic dilatation subjects affected / exposed	3 / 3581 (0.08%)		

occurrences (all)	3		
Aortic dissection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aortic elongation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Aortic stenosis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Aortic thrombosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Arterial disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Arterial occlusive disease			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Arterial stenosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Arteriosclerosis			
subjects affected / exposed	30 / 3581 (0.84%)		
occurrences (all)	31		
Blood pressure fluctuation			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Capillary fragility			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Capillary leak syndrome			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Deep vein thrombosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Diastolic hypotension			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Embolism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Embolism arterial			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Essential hypertension			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Extravasation blood			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Haematoma			
subjects affected / exposed	40 / 3581 (1.12%)		
occurrences (all)	44		
Haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hot flush			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Hyperaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypertension			

subjects affected / exposed	384 / 3581 (10.72%)		
occurrences (all)	441		
Hypertensive angiopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypertensive crisis			
subjects affected / exposed	21 / 3581 (0.59%)		
occurrences (all)	24		
Hypertensive emergency			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	17		
Hypovolaemic shock			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intermittent claudication			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Ischaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Labile blood pressure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lymphostasis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Microangiopathy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		



Orthostatic hypertension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Orthostatic hypotension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral arterial occlusive disease			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Peripheral artery occlusion			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Peripheral artery stenosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral artery thrombosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral circulatory failure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral coldness			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peripheral embolism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral ischaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Peripheral vascular disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peripheral venous disease			
subjects affected / exposed	32 / 3581 (0.89%)		
occurrences (all)	34		

Phlebitis			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	10		
Phlebitis superficial			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Phlebolith			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Poor peripheral circulation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Post thrombotic syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Raynaud's phenomenon			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Shock			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Spider vein			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Subgaleal haematoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Superior vena cava syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Temporal arteritis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thrombophlebitis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		

Thrombophlebitis superficial subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 3		
Thrombosed varicose vein subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Thrombosis subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Varicophlebitis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Varicose ulceration subjects affected / exposed occurrences (all)	7 / 3581 (0.20%) 8		
Varicose vein subjects affected / exposed occurrences (all)	39 / 3581 (1.09%) 40		
Varicose vein ruptured subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Vascular calcification subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Vascular fragility subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Vascular insufficiency subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vascular pain subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vascular rupture subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		

Vasculitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Vasodilatation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vein disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Venous thrombosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Venous thrombosis limb			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Withdrawal hypertension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Surgical and medical procedures			
Abdominal hernia repair			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Artificial crown procedure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bladder repair			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bunion operation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cancer surgery			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cataract operation			
subjects affected / exposed	8 / 3581 (0.22%)		

occurrences (all)	9		
Colectomy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Colostomy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Corneal transplant			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cyst removal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dental care			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dental cleaning			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dental prosthesis placement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dermatofibroma removal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Endodontic procedure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Eye operation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hip arthroplasty			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypotensive anaesthesia procedure			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Inguinal hernia repair			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Intervertebral disc operation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Intraocular lens implant			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Large intestinal polypectomy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Lip operation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nail operation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peripheral nerve operation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Plastic surgery to the face			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rotator cuff repair			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin neoplasm excision			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Spinal fusion surgery			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Suture insertion			
subjects affected / exposed	0 / 3581 (0.00%)		

occurrences (all)	0		
Thyroidectomy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Toe operation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tooth extraction			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	23		
Wisdom teeth removal			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Adenocarcinoma gastric			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Adenoma benign			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Adrenal neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Angiomyolipoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anogenital warts			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Basal cell carcinoma			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	21		

Benign bone neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Benign breast neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Benign gastric neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign lung neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Benign neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign neoplasm of adrenal gland			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign neoplasm of bladder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign neoplasm of cornea			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign neoplasm of skin			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Benign neoplasm of thyroid gland			
subjects affected / exposed	17 / 3581 (0.47%)		
occurrences (all)	17		
Benign ovarian tumour			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		



Benign pleural neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign renal neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Benign salivary gland neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Benign soft tissue neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bowen's disease			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Breast cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Breast fibroma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cancer pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Colon adenoma			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Colon cancer			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ear neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Enchondromatosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Eye naevus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fibroadenoma of breast			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Fibroma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fibromatosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fibrous histiocytoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gastric neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Haemangioma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Haemangioma of bone			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Haemangioma of liver			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Haemangioma of skin			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Hair follicle tumour benign subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Hepatic neoplasm subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Intraductal papilloma of breast subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Invasive ductal breast carcinoma subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Juvenile melanoma benign subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Keratoacanthoma subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Kidney angiomyolipoma subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Leiomyoma subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Lipofibroma subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Lipoma subjects affected / exposed occurrences (all)	8 / 3581 (0.22%) 8		
Lymphoproliferative disorder subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Malignant melanoma in situ subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		

Melanocytic naevus			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Meningioma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Meningioma benign			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Metastases to lung			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Metastases to peritoneum			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Oral haemangioma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Ovarian cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Papillary thyroid cancer			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Polycythaemia vera			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pyogenic granuloma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Renal neoplasm			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Seborrhoeic keratosis			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Skin cancer			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Skin papilloma			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	10		
Squamous cell carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Squamous cell carcinoma of skin			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Sweat gland tumour			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Thyroid adenoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thyroid neoplasm			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Transitional cell carcinoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Uterine leiomyoma			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Immune system disorders			
Allergic oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Allergy to animal			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Allergy to arthropod bite			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Allergy to arthropod sting			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Allergy to chemicals			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Allergy to plants			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Allergy to vaccine			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Atopy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Contrast media allergy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	18		
Food allergy			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Hypersensitivity			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Mite allergy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Multiple allergies			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Rubber sensitivity			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Transplant rejection			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Type I hypersensitivity			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Social circumstances			
Bereavement			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Dental prosthesis user			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Family stress			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Immobile			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Menopause			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Stress at work			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		

Administration site pain			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Administration site reaction			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Adverse drug reaction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Application site bruise			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Application site dermatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Application site eczema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Application site pruritus			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Application site rash			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	117 / 3581 (3.27%)		
occurrences (all)	140		
Axillary pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Calcinosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Catheter site haematoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		



Catheter site pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Chest pain			
subjects affected / exposed	39 / 3581 (1.09%)		
occurrences (all)	40		
Chills			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Crying			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cyst			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	12		
Discomfort			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Drug intolerance			
subjects affected / exposed	14 / 3581 (0.39%)		
occurrences (all)	14		
Exercise tolerance decreased			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Face oedema			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Facial pain			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	8		
Fat tissue increased			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Fatigue			
subjects affected / exposed	61 / 3581 (1.70%)		
occurrences (all)	71		
Feeling abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Feeling cold			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Feeling hot			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	11		
Feeling of body temperature change			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Gait disturbance			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	11		
General physical health deterioration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Generalised oedema			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Granuloma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Impaired healing			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Implant site cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Implant site haematoma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Implant site pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Influenza like illness			
subjects affected / exposed	46 / 3581 (1.28%)		
occurrences (all)	50		
Infusion site bruising			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Infusion site extravasation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	29 / 3581 (0.81%)		
occurrences (all)	32		
Injection site cyst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Injection site dermatitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Injection site erythema			
subjects affected / exposed	56 / 3581 (1.56%)		
occurrences (all)	113		
Injection site haematoma			
subjects affected / exposed	8 / 3581 (0.22%)		
occurrences (all)	9		
Injection site haemorrhage			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	13		
Injection site hypersensitivity			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	8		

Injection site induration			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	5		
Injection site inflammation			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Injection site mass			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Injection site nodule			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Injection site oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	3		
Injection site pain			
subjects affected / exposed	63 / 3581 (1.76%)		
occurrences (all)	94		
Injection site papule			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Injection site paraesthesia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Injection site pruritus			
subjects affected / exposed	28 / 3581 (0.78%)		
occurrences (all)	52		
Injection site rash			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	23		
Injection site reaction			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Injection site swelling			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	37		

Injection site urticaria			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	8		
Injection site warmth			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	3		
Injury associated with device			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ischaemic ulcer			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Local swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Localised oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	25		
Mass			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Medical device pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mucosal dryness			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Mucosal inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Nodule			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		

Non-cardiac chest pain			
subjects affected / exposed	36 / 3581 (1.01%)		
occurrences (all)	38		
Oedema			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	127 / 3581 (3.55%)		
occurrences (all)	139		
Pain			
subjects affected / exposed	45 / 3581 (1.26%)		
occurrences (all)	49		
Pelvic mass			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	34 / 3581 (0.95%)		
occurrences (all)	40		
Polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Puncture site haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Puncture site oedema			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Puncture site pain			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Puncture site reaction			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	58 / 3581 (1.62%)		
occurrences (all)	70		

Sensation of foreign body			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sense of oppression			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Soft tissue inflammation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Suprapubic pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Temperature intolerance			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Thirst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Ulcer haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vaccination site bruising			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vaccination site induration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vaccination site pain			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vessel puncture site bruise			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		

Vessel puncture site erythema subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vessel puncture site haematoma subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vessel puncture site haemorrhage subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Vessel puncture site pain subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vessel puncture site reaction subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Xerosis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Psychiatric disorders			
Abnormal behaviour subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 2		
Abnormal dreams subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Acute stress disorder subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Adjustment disorder subjects affected / exposed occurrences (all)	2 / 3581 (0.06%) 2		
Adjustment disorder with depressed mood subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 3		
Affective disorder			



subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Agitation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Alcohol abuse			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Alcoholic hangover			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	42 / 3581 (1.17%)		
occurrences (all)	42		
Anxiety disorder			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Anxiety disorder due to a general medical condition			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bipolar II disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bipolar disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bruxism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Bulimia nervosa			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Confusional state			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Conversion disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Depressed mood			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Depression			
subjects affected / exposed	78 / 3581 (2.18%)		
occurrences (all)	81		
Depressive symptom			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Emotional disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Encopresis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Feelings of worthlessness			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Grief reaction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Hallucination, auditory			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Head banging			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Illusion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Initial insomnia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Insomnia			
subjects affected / exposed	105 / 3581 (2.93%)		
occurrences (all)	112		
Irritability			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Listless			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Major depression			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mental disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mental fatigue			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Middle insomnia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mood altered			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Mood disorder due to a general medical condition			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nervousness			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Neurosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Nicotine dependence			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Panic attack			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Panic disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Persistent depressive disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Personality change due to a general medical condition			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Post-traumatic stress disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Psychotic disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Psychotic disorder due to a general medical condition			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Restlessness			

subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Schizophreniform disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sleep disorder			
subjects affected / exposed	9 / 3581 (0.25%)		
occurrences (all)	10		
Somatic symptom disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Stress			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Tic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Withdrawal syndrome			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Anisomastia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Atrophic vulvovaginitis			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		
Breast calcifications			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Breast cyst			
subjects affected / exposed	6 / 3581 (0.17%)		
occurrences (all)	6		

Breast discharge			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Breast disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Breast engorgement			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Breast enlargement			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Breast haematoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Breast mass			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Breast pain			
subjects affected / exposed	12 / 3581 (0.34%)		
occurrences (all)	13		
Breast swelling			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Breast ulceration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cervical dysplasia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cervical polyp			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cervix inflammation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Colpocele			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cystocele			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Dysfunctional uterine bleeding			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	4		
Endometrial hyperplasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Endometrial hypoplasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Endometrial thickening			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Fibrocystic breast disease			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Genital atrophy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Genital haemorrhage			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Genital labial adhesions			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Genital prolapse			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Genital rash			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Hydrometra			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hysterocele			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mammary duct ectasia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Menopausal symptoms			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Ovarian cyst			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Pelvic floor muscle weakness			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pelvic haematoma			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Perineal pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Postmenopausal haemorrhage			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Pruritus genital			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rectocele			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		



Urogenital prolapse			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Uterine disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Uterine haemorrhage			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Uterine mass			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Uterine polyp			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Uterine prolapse			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Uterovaginal prolapse			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Vaginal haemorrhage			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	4		
Vaginal polyp			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vaginal prolapse			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Varicocele			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Vulva cyst subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Vulval leukoplakia subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Vulvovaginal dryness subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	6 / 3581 (0.17%) 6		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Acute respiratory distress syndrome subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Allergic bronchitis subjects affected / exposed occurrences (all)	3 / 3581 (0.08%) 4		
Allergic cough subjects affected / exposed occurrences (all)	4 / 3581 (0.11%) 4		
Allergic respiratory symptom subjects affected / exposed occurrences (all)	0 / 3581 (0.00%) 0		
Allergic sinusitis subjects affected / exposed occurrences (all)	1 / 3581 (0.03%) 1		
Asthma subjects affected / exposed occurrences (all)	39 / 3581 (1.09%) 52		
Asthmatic crisis			

subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Atelectasis			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Bronchial hyperreactivity			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Bronchial obstruction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bronchiectasis			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Bronchitis chronic			
subjects affected / exposed	16 / 3581 (0.45%)		
occurrences (all)	19		
Bronchospasm			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Catarrh			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	6		
Chronic obstructive pulmonary disease			
subjects affected / exposed	51 / 3581 (1.42%)		
occurrences (all)	68		
Chronic respiratory failure			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	189 / 3581 (5.28%)		
occurrences (all)	217		
Diaphragmatic abnormal relaxation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Diaphragmatic disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dry throat			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	22 / 3581 (0.61%)		
occurrences (all)	22		
Dyspnoea			
subjects affected / exposed	50 / 3581 (1.40%)		
occurrences (all)	53		
Dyspnoea exertional			
subjects affected / exposed	13 / 3581 (0.36%)		
occurrences (all)	14		
Emphysema			
subjects affected / exposed	11 / 3581 (0.31%)		
occurrences (all)	12		
Epistaxis			
subjects affected / exposed	35 / 3581 (0.98%)		
occurrences (all)	41		
Haemoptysis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Haemothorax			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hydrothorax			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hypoventilation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		

Hypoxia			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Increased bronchial secretion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Increased upper airway secretion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Interstitial lung disease			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Laryngeal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Laryngeal inflammation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Laryngitis allergic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Larynx irritation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lower respiratory tract inflammation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lung consolidation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Lung cyst			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Lung disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		

Lung infiltration			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Mediastinal disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Mouth breathing			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	6		
Nasal discomfort			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nasal dryness			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Nasal mucosal disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Nasal mucosal hypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal obstruction			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal polyps			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		

Nasal pruritus			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal septum deviation			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Nasal septum perforation			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Obstructive airways disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Oropharyngeal discomfort			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	39 / 3581 (1.09%)		
occurrences (all)	44		
Orthopnoea			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pharyngeal inflammation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	3		
Pleural disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		

Pleural thickening			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pleurisy			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pneumonia aspiration			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pneumonitis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pneumothorax			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	20 / 3581 (0.56%)		
occurrences (all)	20		
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulmonary calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulmonary cavitation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulmonary congestion			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		
Pulmonary embolism			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		



Pulmonary fibrosis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Pulmonary granuloma			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pulmonary hypertension			
subjects affected / exposed	18 / 3581 (0.50%)		
occurrences (all)	18		
Pulmonary infarction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Pulmonary mass			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Pulmonary oedema			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Pulmonary pain			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Rales			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Reflux laryngitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Respiratory acidosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Respiratory distress			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		

Respiratory failure			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Rhinalgia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	32 / 3581 (0.89%)		
occurrences (all)	34		
Rhinorrhoea			
subjects affected / exposed	15 / 3581 (0.42%)		
occurrences (all)	15		
Sinus congestion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Sinus disorder			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		
Sinus polyp			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	7 / 3581 (0.20%)		
occurrences (all)	7		
Sneezing			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sputum discoloured			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Sputum retention			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	5 / 3581 (0.14%)		
occurrences (all)	5		

Throat tightness			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Tonsillar hypertrophy			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tonsillar inflammation			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Tonsillolith			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Upper respiratory tract congestion			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Upper respiratory tract inflammation			
subjects affected / exposed	4 / 3581 (0.11%)		
occurrences (all)	4		
Upper-airway cough syndrome			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Vasomotor rhinitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Vocal cord disorder			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Vocal cord thickening			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Bile duct obstruction			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Bile duct stone			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Biliary colic			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Biliary cyst			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Biliary dilatation			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Biliary tract disorder			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Cholangitis			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Cholecystitis			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cholecystitis chronic			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Cholelithiasis			
subjects affected / exposed	37 / 3581 (1.03%)		
occurrences (all)	37		
Drug-induced liver injury			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Fatty liver alcoholic			
subjects affected / exposed	1 / 3581 (0.03%)		

occurrences (all)	1		
Gallbladder cholesterolosis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Gallbladder polyp			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Hepatic calcification			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic cirrhosis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hepatic cyst			
subjects affected / exposed	10 / 3581 (0.28%)		
occurrences (all)	10		
Hepatic failure			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic function abnormal			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic lesion			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatic steatosis			
subjects affected / exposed	35 / 3581 (0.98%)		
occurrences (all)	35		
Hepatitis			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Hepatobiliary disease			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hepatomegaly			
subjects affected / exposed	2 / 3581 (0.06%)		

occurrences (all)	2		
Hydrocholecystis			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hyperbilirubinaemia			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	1		
Hypertransaminaemia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Jaundice			
subjects affected / exposed	2 / 3581 (0.06%)		
occurrences (all)	2		
Liver disorder			
subjects affected / exposed	3 / 3581 (0.08%)		
occurrences (all)	3		
Pneumobilia			
subjects affected / exposed	0 / 3581 (0.00%)		
occurrences (all)	0		
Portal hypertension			
subjects affected / exposed	1 / 3581 (0.03%)		
occurrences (all)	2		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 August 2012	<p>The main goal of Protocol Amendment 1 was to add a coprimary objective to assess the effect of romosozumab treatment for 12 months followed by denosumab treatment for 12 months compared with placebo followed by denosumab on the subject incidence of new vertebral fracture. This addition reflected the chronic nature of osteoporosis in postmenopausal women requiring long-term treatment and facilitated a more complete assessment of the efficacy of a time-limited exposure to romosozumab in such a clinical context. The following changes resulted from the additional objective:</p> <ul style="list-style-type: none"> <li>• Study visit schedule, visit procedures, hypotheses, endpoints, and statistical analysis methods were amended.</li> <li>• Sample size was updated from 5600 to 6000 subjects to allow adequate power to assess the effect of the treatment regimens on reduction in nonvertebral fractures at the end of 24 months.</li> <li>• Safety data reporting was amended to present data over the entire duration of the 24-month study period.</li> </ul> <p>Other substantive updates were as follows:</p> <ul style="list-style-type: none"> <li>• amended exclusion criteria to ensure that bone disorders related to presence of disease/disorder or administration of medications did not confound the assessment of efficacy and safety of romosozumab.</li> <li>• removed exclusion criteria of androgen deprivation therapy</li> <li>• clarified excluded treatments during the study</li> <li>• recommended options in instances of intolerance to protocol required calcium and vitamin D supplementation</li> <li>• clarified investigational product administration procedure</li> <li>• removed denosumab PK assessments</li> <li>• added Serum iPTH and Urinary Calcium substudy</li> <li>• removed month 21 visit since it was not critical for the evaluation of the study objectives</li> <li>• added adjudication of specific events by external experts</li> <li>• added alerting procedure for subjects with loss of <math>\geq 7\%</math> BMD at either the spine or the total hip at month 12</li> <li>• clarified timings of study procedures, assessment of proper anatomic sites, and fasting requirements for blood draws</li> <li>• added acronym (FRAME)</li> </ul>
18 March 2013	<p>The primary goal of Protocol Amendment 2 was is to facilitate enrollment into the Audiology substudy by increasing eligible air-conduction thresholds and airborne gaps. Other substantive updates to the protocol were as follows:</p> <ul style="list-style-type: none"> <li>• clarified that vitamin D loading dose could be given after 1 week postrandomization if the 1-week window was missed</li> <li>• allowed day 1/baseline lumbar spine DXA scan to be taken with the proximal femur DXA scan during screening</li> <li>• clarified procedures for rescreening subjects who did not initially meet the required serum 25 (OH) vitamin D levels</li> <li>• removed requirement to use doxycycline and tetracycline as the only acceptable labels for the month 2 quadruple label procedure for Bone Biopsy substudy. Instead, the Bone Biopsy Manual was referenced for details on the tetracycline derivative labels that were suitable for the quadruple label procedure in order to provide more flexibility in the case of analysis and sourcing constraints.</li> <li>• specified that subjects in the substudies could be replaced while enrollment into the main study was ongoing</li> <li>• clarified expectations for reporting serious adverse events</li> <li>• changed AMG785 to romosozumab</li> </ul>

15 May 2013	<p>The primary goal of Protocol Amendment 3 was to include additional assessments for formation of antiromosozumab antibodies at the month 1 and month 3 main study visits to allow a more comprehensive characterization of the antiromosozumab antibody response, as requested by the FDA. Further changes were made to allow participation of a wider range of patients as follows:</p> <ul style="list-style-type: none"> <li>• lowered age from 60 to 55 (limited to 200 subjects so fracture rate would not be affected)</li> <li>• permitted retesting of serum calcium within the screening window if the initial test indicated an elevated level of serum calcium within 1.1 times the upper limit of normal set by the central laboratory.</li> <li>• revised the protocol-mandated off-treatment times for exclusionary medications</li> </ul> <p>Lastly, this amendment clarified expectations for serious adverse event reporting after the protocol-mandated reporting period had ended.</p>
18 September 2013	<p>The primary goal of Protocol Amendment 4 was 2-fold:</p> <ul style="list-style-type: none"> <li>• to respond to European Medicines Agency request to add an extension period after completion of the initial 24-month study period in which eligible subjects continued to receive open-label denosumab treatment (60 mg SC Q6M) for an additional 12 months while remaining blinded to their initial treatment assignment. Safety endpoints were added at months 30 and 36. Exploratory efficacy endpoints were added at month 36. The primary analysis period was defined as the 24-month study period (ie, after all subjects had the opportunity to complete the month 24 study visit).</li> <li>• to increase the sample size of the main study based on blinded review of on-study nonvertebral fracture data in which the pooled nonvertebral fracture rate was about 12.5% lower than expected under the original protocol assumptions. The assumption that the incidence rate of new vertebral and nonvertebral fracture in the placebo group was 12.5% lower than the original assumptions led to an assumed 2.1% new vertebral fracture rate and an assumed 3.5% nonvertebral fracture rate in the placebo group during the 12-month double-blind period. Using the revised assumptions, the sample size for the study was increased from 6000 to 6600 subjects.</li> </ul> <p>Other substantive updates to the protocol were as follows:</p> <ul style="list-style-type: none"> <li>• removed details relating to the month 12 and month 24 bone biopsy procedures (referred to Bone Biopsy Manual)</li> <li>• updated summary of exclusion criteria to reflect the exclusion criteria revisions incorporated in Amendment 3 (15 May 2013)</li> <li>• added option for subjects to consent to the PK and the Serum iPTH and Urinary Calcium substudies after day 1 (with back-up samples used for any PK time point that may have been missed due to later consenting)</li> <li>• implemented administrative and editorial changes for greater consistency and accuracy</li> </ul>

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported